

04P 02302

81

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau(43) International Publication Date  
2 August 2001 (02.08.2001)

PCT

(10) International Publication Number  
WO 01/55942 A1

(51) International Patent Classification?: G06F 17/60

(21) International Application Number: PCT/US01/02936

(22) International Filing Date: 29 January 2001 (29.01.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/178,634 28 January 2000 (28.01.2000) US

(71) Applicant (for all designated States except US): ACURIAN, INC. [US/US]; 2 Walnut Grove Drive, Suite 375, Horsham, PA 19044 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): TUCKER, Jennifer,

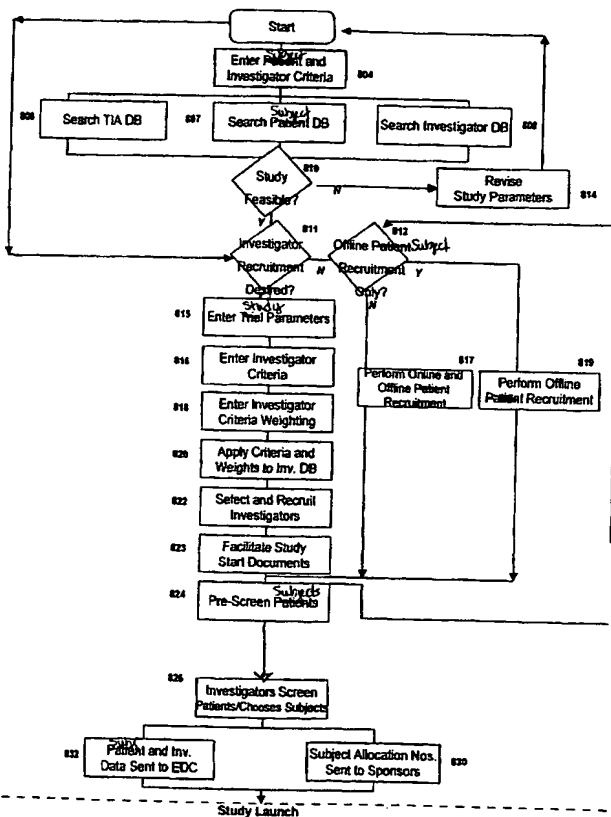
L. [US/US]; 257 Windsor Way, Doylestown, PA 19044 (US). HOLLWAY, John, F. [US/US]; 19 Harrison Drive, Newtown Square, PA 19073 (US). FLORIN, Lawrence, B. [US/US]; 1405 Ringneck Loop, Dresher, PA 19025 (US). HASPIEL, Joseph, B. [US/US]; 17 Arbor Road, St. Louis, MO 63132 (US). CONVERSE, Lance [US/US]; 39 High Gate Lane, Blue Bell, PA 19422 (US). ROSENBERG, Leonard [US/US]; 735 Lippincott Avenue, Moorestown, NJ 08057 (US). MICHELSON, Leslie, Dennis [US/US]; 804 North Whittier Drive, Beverly Hills, CA 90210 (US). JAMES, Steven, P. [US/US]; 13292 Seagrove Street, San Diego, CA 92130 (US).

(74) Agent: GOLUB, Daniel, H.; Morgan, Lewis &amp; Bockius LLP, 1701 Market Street, Philadelphia, PA 19103 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,

[Continued on next page]

(54) Title: SYSTEMS AND METHODS FOR SELECTING AND RECRUITING INVESTIGATORS AND SUBJECTS FOR CLINICAL STUDIES



(57) Abstract: The present invention is directed to an integrated on-line interactive forum that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subjects. The forum includes an investigator database (808) that contains information suitable for identification of qualified investigators (811) for clinical studies and a subject database (807) that contains information suitable for identification of eligible subjects for clinical studies (817, 819). An extranet is coupled to the investigator database and the subject database. The extranet allows sponsors and investigators to exchange securely documents required to start a clinical study (830). The forum also optionally includes one or more web pages that provide information describing clinical studies to potential clinical study subjects and permit potential clinical study subjects to register for inclusion in the subject database. A therapeutic incidence area database (806) is also optionally integrated into the forum.

WO 01/55942 A1



LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ,  
NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,  
TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

- (84) **Designated States (regional):** ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— with international search report

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

SYSTEMS AND METHODS FOR SELECTING AND RECRUITING  
INVESTIGATORS AND SUBJECTS FOR CLINICAL STUDIES

Cross-Reference To Related Application

The present application claims priority to U.S. provisional application no. 60/178,634, filed January 28, 2000, entitled "Method and System for Creating And Managing Databases for Clinical Trials," the contents of which are hereby incorporated herein in their entirety by reference.

Field of the Invention

The present invention relates to a novel integrated on-line interactive forum that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subjects. In addition, the present invention relates to novel systems and methods for selecting and recruiting subjects and investigators for clinical studies.

Background of the Invention

The increase in the breadth and specificity of research and development for the purposes of identifying and qualifying new drugs and devices for a wide variety of therapeutic areas has resulted in an increase in the specificity and number of subjects and qualified investigators needed by medical and pharmaceutical companies to participate in clinical studies.

Recruitment of a number of clinical study subjects sufficient to establish the safety and efficacy of a drug or device on specific clinical subject populations is essential for the success of clinical study, and therefore for the obtaining of the regulatory approvals necessary for marketing the drug or device on a world wide basis. Recruiting clinical subjects has been complicated by, among other things, the specificity of the new therapies, the increase in the number and breadth

of clinical studies required by regulatory authorities, and the globalization of the clinical trial process.

The increased complexity of therapies, primarily the result of advances in the application of biotechnology and combinatorial chemistry, has resulted in increased requirements for additional clinical studies from regulatory agencies. In addition, the requirements of managed care companies for more additional outcome information results in a growing demand for clinical studies. This, in turn, increases the pressure to identify adequate numbers of clinical subjects and qualified clinical investigators. Where traditionally a large number of the clinical studies in a particular therapeutic area were conducted by a small number of clinical investigators, the increase in demand makes it necessary for additional physicians to become trained in the conduct of clinical trials, new means to be developed to recruit subjects, and a broadening of the scope of the search for qualified clinical investigators.

The increased complexity of therapies has been marked by a trend away from the mass treatment mentality of the past, toward treatment of an individual based on the individual's specific characteristics. For example, new therapies are being developed that are specifically designed to interface with an individual's genome. This necessitates the use of clinical subjects that share certain genetic characteristics. This means that the pool of clinical subjects is naturally smaller, and creates a need to draw from a broader base of individuals in order to identify sufficient numbers of eligible participants to complete a clinical study. Handling of the sensitive information identifying an individual's potential genetic propensities implicates certain privacy issues, and add an additional layer of complication to the clinical study recruitment process. Many subjects are concerned that if, for example, they are found to have a particular genetic



propensity for certain diseases in the course of a study that they may have difficulty obtaining health coverage.

The result of the foregoing has been an increase in the number of clinical studies, and hence the need to identify qualified investigators and eligible individuals, in geographic locations other than the country wielding regulatory authority. The ability to advance a clinical study simultaneously in many locations, and locating qualified investigators and eligible subjects, increases the likelihood that the clinical study will be completed with minimal delays. Delays are extremely costly to clinical study sponsors because each day a new drug is delayed from reaching the market results in lost revenue and, potentially, lost exclusivity and a later market entry. Delays and the high costs associated with launching a clinical study are some of the biggest obstacles to bringing a new drug to market.

Thus, there exists a need to provide a global means to facilitate the identification and communication between clinical sponsors, clinical investigators and eligible clinical subjects to expedite the process of launching clinical studies in an efficient and cost-effective manner.

#### Summary of the Invention

The present invention is directed to an integrated on-line interactive forum that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subjects. The forum includes an investigator database that contains information suitable for identification of qualified investigators for clinical studies sponsored by the sponsors, and a subject database that contains information suitable for identification of eligible subjects for clinical studies sponsored by the sponsors. An extranet is coupled to the investigator database and the subject database. The extranet permits the secure exchange between sponsors and investigators of documents required prior to the start of a clinical study.

The forum also optionally includes one or more web pages that provide information describing clinical studies to potential clinical study subjects and permit potential clinical study subjects to register for inclusion in the subject database. A therapeutic incidence area database is also optionally integrated into the forum.

The present invention is also directed to a method for recruiting a person to participate as a subject in a clinical study. One or more web pages are presented that allow the person or a caregiver associated with the person to register with a database by submitting registration and permission information to the database. The registration information includes, for example, a user id, a password, preferred contact information (i.e., an electronic mail address or telephone number), zip code, first name or preferred name, gender, date of birth, whether the person or caregiver is interested in clinical study information, and whether the person or caregiver is interested in new medical therapies. The permission information includes whether the person or caregiver is interested in receiving notice of clinical studies. The person or caregiver is automatically registered with the database upon receipt of the registration and permission information. Next, an automatic determination is made, in accordance with the permission information and the registration information, as to whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person. The person or caregiver is provided notice of the given clinical study only if the system automatically determines that such notice should be sent. A questionnaire associated with the given clinical study may also be provided automatically to the person or caregiver, if the person or caregiver indicates interest in the clinical study in response to the notice. Answers submitted by the person or caregiver to the questionnaire are then stored in the database. The stored questionnaire answers, along with other information stored in the database, may be accessed to

determine whether the person should be pre-screened for participation as a subject in a clinical study different from the given clinical study.

In another embodiment, the present invention is directed to a further method for identifying subjects eligible to participate in a clinical study. A computer database that stores information about a plurality of persons is accessed. For each person listed in the database, the database includes a geographic location of the person, an age and a gender of the person, medications taken by the person, and disease conditions of interest to the person. A query is submitted to the database. The query includes criteria that reflect eligibility characteristics for persons suitable for use as subjects in the clinical study. De-identified data records of persons likely to be subjects eligible for the clinical study are selected based on the query. The feasibility of the clinical study may next be evaluated based on the de-identified data records returned from the query. The feasibility of the study can then be further explored by modifying the criteria used to query the database and repeating the above steps using the modified criteria.

The present invention also includes a method for identifying a qualified investigator to perform a clinical study. At least one computer database that stores a geographic location of each of a plurality of investigators is accessed. The at least one database also stores an incidence or a prevalence of each of a plurality of disease conditions in each of a plurality of different geographic locations. At least one query that includes information representing a selected disease condition associated with the clinical study is submitted to the at least one database. The qualified investigator is identified from the at least one database based on the query and in accordance with the incidence or prevalence of the selected disease condition in the geographic location of or proximate to the qualified investigator.

The present invention includes a further method for identifying a qualified investigator to perform a clinical study. In this further method, at least one computer database stores a geographic location of each of a plurality of investigators is accessed, wherein the database also stores a geographic location of subjects proximate to each of the plurality of investigators. A query that includes information representing a selected disease condition associated with the clinical study is submitted to the at least one database. The qualified investigator is identified from the at least one database based on the query and in accordance with the geographic location of subjects proximate to the qualified investigator. The at least one database also optionally stores an incidence or a prevalence of each of a plurality of disease conditions in each of a plurality of different geographic locations, and the qualified investigator is identified from the database based also on the incidence or prevalence of the selected disease condition in the geographic location of the qualified investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the prescription writing history of the investigator with respect to a plurality of medications. The database also optionally stores information that associates each of the medications with one or more disease conditions. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the given investigator's prescription writing history.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality

of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the history of laboratory procedure requests made by the investigator. The database also optionally stores information that associates each of the laboratory procedure requests with one or more disease conditions. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the given investigator's history of laboratory procedure requests.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to past participation of the investigator in clinical studies. A query that may include information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the given investigator's past participation in clinical studies.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to a medical specialty of the investigator. The database also optionally stores information that associates each medical specialty of an investigator with one or more disease conditions. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is

identified from the database based on the query and in accordance with the given investigator's medical specialty.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the experience of the medical staff of the investigator. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the experience of the medical staff of the investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to how many clinical studies have been performed by the investigator. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with how many clinical studies have been performed by the investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to a hospital affiliate of the investigator. A query that includes information representing a selected disease condition associated with the study is

submitted to the database. A given investigator is identified from the database based on the query and in accordance with the given investigator's hospital affiliation.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to claims data of the investigator. The database also optionally stores information that associates claims data of the investigator with one or more disease conditions. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the given investigator's claims data.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the number of beds in the hospital affiliate of the investigator. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the number of beds in the hospital affiliate of the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the insurance provider affiliations of the investigator. A query that includes information representing a selected disease condition associated with the

study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the insurance provider affiliations of the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to any Institutional Review Board ("IRB") affiliation of the investigator. The database also optionally stores information that associates each IRB. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the mandated IRB relationships of the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to FDA or other regulatory agency audits of the investigator. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with regulatory agency audits of the investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to any Primary Research Facility ("PRF") affiliation of the investigator. The database also optionally stores information that associates each PRF affiliation. A query that includes information representing a selected disease condition



associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the PRF affiliations of the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to equipment available to the investigator. The database also optionally stores information that associates various pieces of equipment with one or more disease conditions. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the equipment available to the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the practice setting of the investigator. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the practice setting of the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the investigator's city and state of practice. A further

database also optionally stores information that associates the investigator's city and state of practice with one or more disease conditions. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the investigator's city and state of practice.

The present invention is also directed to a method for developing a permission based online database. One or more web pages are presented that allow a person to register with a database by submitting registration and permission information to the database. The registration information includes name information and contact information and the permission information indicates whether the person wishes to receive notice of one or more clinical studies. The person is automatically registered with the database upon receipt of the registration and permission information. Permission is obtained to send the person marketing information about drugs, medical devices or medical therapies. The database is added to by repeating the above steps for a plurality of persons. Next, a list is generated for use in marketing drugs, medical devices and medical therapies to subjects by querying the database using criteria associated with the drugs, medical devices and medical therapies.

The present invention is also directed to a method of maintaining the confidentiality of clinical study information associated with a plurality of clinical study sponsors. Clinical study information is received from a plurality of clinical study sponsors, and stored in a database. Each sponsor is permitted full access in the database to clinical study information submitted by that sponsor. Each sponsor is permitted limited, de-identified aggregated access to information submitted by other sponsors. The clinical study information submitted by each sponsor optionally includes any combination of: investigator information, sponsor identification,

protocol information, drug indication information, drug class information, clinical study enrollment goal information, actual clinical study enrollment information, and information on the number of clinically evaluable subjects.

#### Brief Description of the Drawings

Fig. 1A is a block diagram showing the connection over a computer network of additional computers to the integrated, on-line interactive forum of the present invention.

Fig. 1B is a block diagram showing the components of the integrated, on-line interactive system of the present invention.

Figs. 2A and 2B depict an exemplary Internet web page used for registering persons in a database used for identifying eligible subjects for a clinical study, in accordance with the present invention.

Fig. 3 depicts an exemplary web page used by a person to submit geographic and contact information to a database used for identifying eligible subjects for a clinical study, in accordance with the present invention.

Figs. 4A, 4B and 4C depict an exemplary web page through which a person submits one or more disease conditions of interest to a database for identifying eligible subjects for a clinical study, in accordance with the present invention.

Figs. 5A through 5F depict an exemplary web page which conveys to a registered user information about clinical studies, in accordance with the present invention.

Figs. 6A through 6N depict a series of exemplary web pages through which a person can search clinical studies and opt to receive information about clinical studies in one or more selected therapeutic areas, in accordance with the present invention.

Figs. 7A, 7B and 7C depict an exemplary web page that provides a questionnaire that may be completed by an investigator interested in conducting a clinical study, in accordance with the present invention.

Fig. 7D to 7G depict flow diagrams showing processes for registering subjects and investigators, in accordance with alternative embodiments of the present invention.

Fig. 8 is a flow diagram showing the steps performed by a sponsor using the professional site to recruit subjects, investigators, and take steps necessary to start a clinical study.

Fig. 9 is an exemplary web page used by a sponsor to enter study parameters into the system.

Fig. 10 is an exemplary web page used by a sponsor to enter criteria necessary to initiate an investigator search.

Figs. 11A and 11B depict an exemplary web page showing the search results from an investigator search performed using the present invention.

Figs. 12-13 are exemplary web pages showing an extranet for creating, sending and tracking documents necessary to start a clinical study.

Figs. 14 is an exemplary electronic mail notification used for contacting a potential subject for a clinical study.

Fig. 15A through 15F is an exemplary study-specific subject questionnaire used for prescreening a subject for a clinical study.

Fig. 16 is a process flow diagram showing the steps of a method for identifying persons to participate in a clinical study, in accordance with a further embodiment of the present invention.

Fig. 17 is a process flow diagram of a method for identifying eligible investigators for a clinical study, in accordance with one embodiment of the present invention.

Fig. 18 is a process flow diagram showing the steps of a method for identifying eligible investigators for a clinical study, in accordance with an alternate embodiment of the present invention.

Fig. 19 is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study, in accordance with a still further embodiment of the present invention.

Fig. 20 is a process flow diagram showing the steps of a method for recruiting a person to participate in a clinical study, in accordance with the present invention.

Figs. 21A – 21Q show the steps of various methods of recruiting investigators in accordance with alternative embodiments of the present invention.

Figs. 22A through 22F depict an exemplary data structure for implementing an investigator database, in accordance with the present invention.

Figs. 22G-K depict use of a disease incidence search on a TIA database to assist in performing investigator and subject selection, in accordance with the present invention.

Fig. 23 is a screen shot showing sponsor access limitations to study data.

Figs. 24A through 24D depict an exemplary data structure for implementing a subject database, in accordance with the present invention.

Fig. 25 depicts an exemplary data structure for implementing a study listings database, in accordance with the present invention.

Fig. 26 depicts an exemplary data structure used for implementing the sponsor access limitations shown in Fig. 23.

Fig. 27 is a flow diagram of a method for performing permission-based electronic mail marketing to consumers, in accordance with the present invention.

#### Detailed Description of the Preferred Embodiments

For purposes of the present invention, each of the terms set forth below shall be defined in accordance with the corresponding definitions set forth below:

“Clinical Investigator” or “Investigator” shall mean the Person with regulatory responsibility for conducting a Clinical Study.

“Clinical Study(ies)” shall mean studies designed to distinguish the effect(s) of a drug or a medical device on humans from other influences--for example, a spontaneous change in disease progression or in the effect of a placebo (an inactive substance that looks like the test drug).

“Clinical study sponsor” or “sponsor” shall mean any person responsible for conducting or overseeing a clinical study or trial, including, without limitation, pharmaceutical companies, clinical research organizations, biotechnology companies, medical diagnostic companies, medical device companies or other entities.

“Clinical Subject” or “Subject” shall mean the human subject of a Clinical Study or a potential human subject of a Clinical Study.

“Clinical trials” shall mean those clinical studies required to achieve regulatory approval.

“Consent Information” shall mean that information required by applicable law and/or regulation in order to properly consent to the disclosure of confidential subject information.

“Contract Research Organization” or “CRO” shall mean an organization that receives services relating to conduct of clinical studies.

“Disease Condition” means any human disease or condition for which a Clinical Study may be conducted, including without limitation, a physiological, physical, psychological, psychiatric, surgical or post-surgical condition, whether or not manifest by symptoms. It also includes conditions definable by the existence or omission of a particular genotype, phenotype, or other genetic structure or ordering of genetic material.

“Electronic data capture” or “EDC” shall mean a company in the business of providing software that collects data through the conduct of a clinical study.

“Extranet” shall mean a web application that works over the Internet for sharing data with specific users. Access to the application is protected by the use of passwords, encryption and other security mechanisms.

“Identifying Information” shall mean any individually identifiable health information transmitted in the course of recruiting clinical subjects that relates to an individual’s physical or mental health or condition, and/or the provision or payment of care, and that identifies the individual or creates a reasonable basis to believe the information can be used to identify the individual.

“De-identified Data” shall mean data in which identifying information has been removed or hidden by removing, coding, encrypting, or otherwise eliminating or concealing the information such as name, address, birth date, name of relatives or employers, telephone numbers, email address and other unique identifying numbers, characteristics or codes that the covered entity had reason to believe may be used by an anticipated recipient of the information to identify the individual.

“IRB” shall mean “Institutional Review Board”. Other countries may have equivalent such ethics boards under International Health Commission (“IHC”) guidelines.

“Investigational Drug or Device” shall mean any drug or device that is the substance or object being tested in a Clinical Study; including without limitation, drugs or devices designed for the cure, prevention, control, monitoring of treatment or treatment of a Disease Condition.

“Laws” shall mean all applicable laws, statutes, rules, regulations, ordinances and other applicable pronouncements having the effect of law whether federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign which pertain to and are applicable to the disclosure of confidential subject information including subject identity.

“Permission Information” shall mean optional information submitted by a user of a database in order to convey the user’s agreement to receive data or information or to have personal and/or confidential information provided by the user disclosed under certain defined circumstances.

“Person” shall mean any individual, corporation, partnership, association, unincorporated organization or government or political subdivisions thereof.

“Primary research facility” or “PRF” shall mean the location at which the investigator conducts a clinical study.

“Regulatory Approval” shall mean, with respect to a country, all authorizations by the appropriate governmental entity or entities necessary for commercial sale of a drug product in that country including, without limitation and where applicable, approval of labeling, price, reimbursement and manufacturing. “Regulatory Approval” in the United States shall mean final approval of a new drug application pursuant to 21 C.F.R. § 314, permitting marketing of a drug product in interstate commerce in the United States.



### System Architecture

Referring first to Figure 1A, in that figure is depicted computer network 103 operatively connecting computer system 100 to more or more additional computer systems represented here as computer systems 101 and 102. Computer system 100, described in more detail below, may be any of a number of commercially available computer systems, including a conventional server or workstation. Such systems may include, for example, one or more microprocessors, computer memory, conventional communication circuitry (e.g., a modem) and other commonly available peripherals. Computer systems 101 and 102, and other computers that interface with network 103, may also be such workstations or servers, or may comprise any type of commercially available personal computers capable of communicating over a computer network. Those of ordinary skill in the art will recognize that network 103 may connect to any number of additional computers. Network 103 represents a public or private computer network. The Internet is one example of such a network, though other types of networks are possible within the scope of the inventions described herein.

Referring now to Figure 1B, there is shown a block diagram of an integrated online system 100 that promotes exchange of information among clinical study sponsors, clinical study investigators, and clinical study subjects, in accordance with the present invention. The clinical study sponsors, investigators and subjects may access system 100 using computers such as computers 101, 102. Among other things, system 100 serves to integrate the now fragmented clinical study system by bringing clinical study sponsors, clinical study investigators, and subjects together in a common environment. The system 100 also serves to integrate the clinical study system by bringing the clinical study sponsors, clinical study investigators and subject's data together in a secure environment. In addition, and as discussed more fully below, system

100 includes specialized databases and collaboration tools that allow clinical study sponsors and investigators to take the steps necessary to start a clinical study more quickly, including assessing the feasibility of a study, locating qualified investigators, communicating with investigators, completing all required preliminary documentation necessary to enroll investigators in the study, locating qualified and interested subjects, communicating with interested subjects, and directing interested subjects to appropriate investigator sites to perform the physical assessment and complete the necessary documentation to enroll the subjects in the clinical study.

System 100 contains several databases, that function in combination to facilitate the start of a clinical study. By way of an overview, system 100 includes a subject database that includes information about persons that may potentially qualify as eligible subjects for a clinical study. Demographic information about each registered person is stored in the subject database. In addition, information about disease conditions of interest to persons in the subject database and information about clinical studies of interest to such persons is stored in the subject database. As a potential subject interacts with system 100 over time by, for example, attempting to qualify for participation in various clinical studies, system 100 collects and stores additional information about the persons represented in the subject database. In accordance with this aspect, individual subjects or their caregivers will enter information about themselves into system 100 when they attempt to qualify for a given clinical study. This information may be limited to what is sought in the registration questionnaire, or it may take the form of responses to one or more different questionnaires designed to assess eligibility for a given clinical study. Irrespective of whether the subject is ultimately selected for participation in the study, upon obtaining appropriate consent from the subject, the information entered by the subject during any pre-screening for the

clinical study will be added to the registration information and stored as part of the subject database. Over time, as a given individual attempts to qualify for further clinical studies, still further information will be collected about the individual in connection with the screening for the further clinical studies. This further information will also be stored in the subject database. Thus, over time, the information in the subject database will grow more detailed and complete as the same individual provides additional information to apply for additional studies using system 100. As discussed more fully below, the subject database is used by clinical study sponsors to identify potential subjects to participate in clinical studies. As the information stored in the subject database becomes more detailed and complete over time, the utility of the subject database will be further enhanced from the point of view of clinical study sponsors because the sponsors will be able to identify more rapidly, accurately and with higher confidence potential subjects for their clinical studies.

In system 100, potential clinical study subjects submit data (later stored in the subject database) through the subject site. The subject site is, for example, an internet website that is accessible to the general population. Further details of the subject site are shown in Figs. 2 through 6, and discussed below. By way of overview, the subject site includes content about new medical therapies and current clinical studies. This content is typically of interest to chronically ill persons, persons who are newly diagnosed with a particular illness, caregivers for persons with a particular illness, and other persons in the general population who might be interested in participating as subjects in a clinical study. The content is preferably available for free to the users. However, when viewing the content, users are requested to register with the subject site. During the registration process, a given user will enter demographic information about himself or herself, and will be given an opportunity to indicate areas of new medical

therapies or clinical studies that are of interest to the individual. All such information entered by the user is stored in the subject database. As discussed more fully below, if a registered user wishes to attempt to qualify for participation in a clinical study, the individual may submit answers to a questionnaire tailored to the clinical study via the subject site. (In one embodiment, the questionnaire answers are received from the subject or caregiver on a secure page of the subject website.) These questionnaire answers are then used for at least three purposes. First, the answers are used to pre-screen the individual for the given clinical study for which they are attempting to qualify. Second, with appropriate consent from the individual, the questionnaire answers are stored in the subject database and used to assess more accurately whether or not the given individual would be appropriate for consideration in a later clinical study. Third, the questionnaire answers are used to assess the feasibility of subsequent studies. Fourth, the answers may be used to lock-out people once they are in a study.

Referring still to Figure 1, system 100 also includes an integrated investigator database. In one embodiment, the investigator database includes information from three general sources as described below, although in other embodiments it may include information from a lesser or greater numbers of sources or different sources. First, the investigator database includes data about the clinical study investigators who wish to inform clinical study sponsors of their clinical study experience and/or training, submitted by the investigators themselves. This self-reported data is typically entered into the investigator database either when a given investigator logs onto the professional site, and registers with the system as described further with reference to Figs. 7A through 7C or by submitting such information to the professional site by mail, fax, phone or other non-computerized means. The self-reported data includes various types of information including, for example, the educational background of the investigator, the clinical study

experience of the investigator, the past performance of the investigator in other clinical studies (e.g., how many subjects the investigator committed to recruit for a given study in what period of time, how many subjects the investigator actually recruited for the study in what period of time, and how many of such subjects actually completed the study), equipment available to the investigator (e.g., whether or not the investigator has access to a CAT scan machine or MRI equipment which may be required for a given study), any mandated IRB relationships of the investigator (e.g., whether or not the investigator is required through professional affiliations to submit materials to a particular IRB for approval before the materials may be used to advertise the study), any hospital or HMO affiliations of the investigator, information about the investigator's staff and facilities and the geographic location of the investigator.

In addition to the self-reported information, the investigator database also includes information about investigators received from a variety of external sources. One such external source is the FDA, which can provide information about any past clinical studies for which an investigator has registered, as well as any information about sanctions or other disciplinary actions that may have been issued in connection with an investigator's work in a past clinical study. Information obtained from the investigator in the past or from other third party sources, such as an investigator's prescription writing history and the history of laboratory requests made or lab results received by an investigator in the past, are stored in the investigator database. Such external information can be used to both supplement and verify the self-reported data entered by the investigator and discussed above. Clinical study sponsors may also supply information about their past experiences with a given investigator, and such information may be stored in the investigator database.

In addition to the self-reported and external source data, additional information about a given investigator will be learned by system 100 as the investigator interacts with system 100 and attempts to enroll in clinical studies with the assistance of the system. For example, in some embodiments, after a given clinical investigator has been recruited for a given clinical study using system 100, the system will monitor the investigator's performance with respect to the clinical study and store this performance data in the investigator database if the system is linked to an EDC product that is collecting data throughout the study. In alternative embodiments, the performance data may be obtained through off-line sources.

In an embodiment, system 100 also includes a Therapeutic Incidence Area ("TIA") database. The TIA database contains the incidence and/or prevalence of different disease conditions by geographic area. Thus, for example, the TIA database may store the incidence or prevalence of colon cancer in each of several different municipalities across the country. The data sets and search parameters used to conduct searches in the TIA databases have been created to conform to the information required by clinical study sponsors when determining the likelihood of recruitment success within the projected time frame for a particular protocol for the study, or when determining where to locate investigator sites to conduct the study. As explained more fully below, the present invention uses the TIA database to assist in the selection of investigators for a given clinical study by searching for an investigator who is proximate to a geographic area where a greater number of subjects who may be eligible to participate in the study reside or receive treatment.

An important part of system 100 is its incorporation of an extranet to facilitate secure collaborations between a clinical study sponsor (or its designees) and its investigator(s) during the process leading up to the start of a clinical study. As discussed more fully below, after a

clinical study sponsor has identified an investigator to perform a given clinical study, the sponsor must formally engage the investigator for the study. During the engagement process, several documents (e.g., an investigator questionnaire, answers to the investigator questionnaire, a confidentiality agreement, a contract, a budget, an FDA form 1572, IRB documents, the study protocol, etc.) will in most instances be exchanged between the sponsor and the investigator. The present invention provides a secure environment for these communications, as well as functionality that manages and tracks the documents needed to start the clinical study. In one embodiment, this functionality is achieved by allocating individual workspaces to sponsors and investigators within the professional site. A given sponsor or investigator is then able to receive, send, and track documents from within his or her workspace.

#### **Subject Site and Registration**

Information regarding potential clinical study subjects may be gathered from a variety of different sources including, in a preferred embodiment, via a web site such as subject site of Fig. 1B. The information obtained regarding potential clinical study subjects must be sufficiently general in nature such that it may be applicable to a variety of different therapeutic areas and disease conditions, yet specific enough to be useful in assessing the subject's eligibility for a specific study with narrowly defined inclusion or exclusion criteria.

Figs. 2A and 2B depict an exemplary internet web page, which allows for the registration of persons in a database (e.g., the subject database of Fig. 1B) and which is used for identifying eligible subjects for a clinical study, in accordance with the present invention. Registration web page 200 includes e-mail area 201, username area 202, and password area 203 where the person registering in the database may enter his or her information. A hypertext link 204 to a privacy and security policy of the service provider may be provided in some embodiments. In all

embodiments, the privacy of subjects is protected by ensuring compliance with all applicable laws. A question/answer area 205 may be provided for use in the event the person forgets his or her password. In agreement area 206, the terms and conditions pursuant to which the person is entitled to register himself or herself in the subject database and use the inventive system may be provided.

Fig. 3 depicts an exemplary web page of subject site used by a person to submit geographic, gender and contact information to a database, such as the subject database of Fig. 1B, used for identifying eligible subjects for a clinical study, in accordance with the present invention. Personal information web page 300 includes name, contact information, and geographic information area 301 as well as gender information area 302 where the person registering in the database enters his or her information.

Figs. 4A through 4C depict an exemplary web page of subject site through which a person may submit one or more disease conditions to a database for identifying eligible subjects for a clinical study, in accordance with the present invention. Therapeutic area web page 400 includes pull down menu 401 at which a person may identify a therapeutic area of interest to that person. In this example, the therapeutic area cancer has been chosen. Upon clicking on view button 402, the potential disease conditions of interest are presented to the subject or caregiver in disease condition area 403. The person may check one or more boxes in medical news/drug area 404 or clinical study opportunities area 405 to indicate if the person is interested in obtaining medical news, drug or clinical study opportunity information on any of the disease conditions specified in disease condition area 403.

Figs. 5A through 5F depict an exemplary web page of the subject site, which conveys information about clinical studies, and an ability to search clinical studies to a registered user, in



accordance with the present invention. Frequently asked questions area 503 is provided to educate a person on clinical studies. In search area 501, the registered user may click on any one of the therapeutic areas identified (such as cancer clinical study area 502) and be taken to a search clinical study web page 600, as depicted in Figs. 6A and 6B.

Search clinical studies web page 600 allows the user to search for clinical studies relating to the therapeutic area identified in search area 501. Search clinical study web page 600 includes search area 601 which allows the user to use particular search criteria to find clinical studies. For example the user may select a condition in condition area 602 and/or may select a state in location area 603. The user may also select a particular geographic location, in location area 603. The user may indicate in contact area 604 that the person wishes to be contacted for a particular clinical study.

Upon clicking on contact area 604, the user will be taken to general study interest web page 605 shown in Fig. 6C. On general study interest web page 605, the registered user may indicate in interest area 606 whether the registered user is interested for himself/herself or for someone else. In one embodiment, the registered user may select in selection area 607 up to three therapeutic areas in which the registered user is interested. In contact area 608, the registered user indicates the manner in which the registered user would like to be contacted, e.g., by e-mail, telephone or regular mail. The registered user also indicates name and contact information in contact information area 609. The registered user submits the form by clicking on submit button 610, or may cancel the process by clicking on cancel button 611.

In other embodiments, the above-referenced information may be included in the database and entered via the web site not by the subject but by a caregiver of the subject. The caregiver

may be anyone who is providing care to the subject, such as a medical professional, a family member, or a friend.

In an alternative embodiment, in order to become a user registered with the subject database, the user will be required to provide the information required as shown in the web page depicted in Fig. 6D: a user id; password; password reminder; and whether the user is seeking information for himself or herself or for someone else. In a second step, with reference to Fig. 6E, the user will be required to provide additional information such as first name, date of birth, gender, electronic mail address, zip code and an indication of one or more medical conditions in which the user is interested. Additional information, though not required for registration, may be provided such as medical conditions experienced by the user, salutation, last name, ethnic background, telephone number, country of residence, as shown in Fig. 6E. In a third step 3, the user inputs information on a web page such as that shown in Fig. 6F, including a request to receive various types of information (such as, e.g., clinical study opportunities or news and new medical therapies) about the user's medical conditions identified in Fig. 6E. The user may request that he or she not be sent any information. In area 650, the user is asked to agree to certain terms and conditions governing the user's use of the inventive system.

Upon completing the required information and accepting the terms and conditions, the user will become a registered user of the inventive system, as shown in the web page depicted in Fig. 6G. At this point, the user may choose to answer additional, optional questions or to return to the previous activity. If the user chooses to answer additional questions, the user may be taken to a web pages such as those depicted in Figs. 6H through 6J and provide information such as the type of prescriptions or over-the-counter medications taken by the user for a given medical condition; the health habits of the user; and the clinical study experience of the user. In Fig. 6K,

the user can see if the user has answered completely questions about each medical condition previously listed by the user. In Fig. 6L, the user can provide feedback. In Fig. 6M, the service provider may provide a thank you to indicate that the message was sent successfully.

The registered user may also access, on the subject site, the registered user's own personal library. Library web page 612, shown in Fig. 6N, informs the registered user that he or she may maintain a personal library of information relating to clinical studies or new developments related to particular therapeutic areas found throughout the subject site. The user may also create and save personal notes relating to the same. Information may be placed in the library by the registered user or, in some embodiments, specific information on topics which may be of interest to the registered user may be placed in the registered user's library automatically based on, for example, the registered user's past selections of information to place in the library, therapeutic areas of interest, disease conditions of interest, geographic location, and/or gender.

#### **Investigator Registration on Professional Site**

An investigator who is interested in conducting clinical studies may express his or her interest by registering on the professional site of Fig. 1B. Figs. 7A, 7B and 7C depict investigator questionnaire web page 700 that provides a questionnaire that may be completed by an investigator interested in conducting a clinical study, in accordance with an embodiment of the present invention. In name area 701, the investigator is required to input his or her name. In degree area 702, the investigator's degree(s) are required. The PRF organization or institutional name, address, city state, country, zip code and telephone number are required (and fax and electronic mail address optionally requested) in contact area 703. Specialty area 704 requires that the investigator provide his or her primary specialty area. Board area 705 requires that the investigator indicate whether he or she is board certified and/or board eligible; optionally, the

investigator's year of primary specialty board certification, and board information regarding any of the investigator's subspecialties may be provided. In study experience area 706, the investigator is required to indicate the number of years the investigator has participated in clinical studies as well as all phases of clinical research in which the investigator has participated. The investigator must include the number of investigators that conduct research at the PRF indicated in investigator area 707.

Additional information may also be provided regarding, for example, the following: the IRB with which the investigator is associated, as indicated in IRB area 708; any audits of the investigator conducted by the FDA or other regulatory agency, as indicated in FDA audit area 709; any audits of the investigator conducted by a sponsor or CRO, as indicated in sponsor audit area 710; and/or information about the investigator's PRF, such as whether it is single specialty, multi-specialty, part of a solo or group practice, or affiliated with a site management organization or research group, as indicated in PRF area 711. In alternative embodiments, an investigator provides the information requested in the investigator questionnaire by phone, fax, regular mail or other non-computerized means, rather than transmitting the information to the professional site on-line.

In addition to the information described above, an investigator may be required to include information regarding his or her publications and educational background; hospitals or PRF with which the investigator is associated; health plans with which the investigator is associated; equipment to which the investigator has access; and any sanctions imposed by the FDA or other regulatory agency upon the investigator.

### **Alternative Embodiments For Subject and Investigator Registration**

Fig. 7D to 7G depict flow diagrams showing processes for registering subjects and investigators, in accordance with alternative embodiments of the present invention. Fig. 7D is directed to persons that register with the subject or investigator site based on a visit to the subject site; Fig. 7E is directed to persons that register with the subject or investigator site based on a contact with a pharmaceutical call center; Fig. 7F is directed to persons that register with the subject or investigator site based on a contact with an off-line call center; and Fig. 7G is directed to persons that register with the subject or investigator site based on a visit to a third party on-line recruitment site.

### **Study Feasibility and Launch Process**

Referring now to Figure 8, there is shown a flow diagram of a process that may be used by a sponsor to accomplish the steps necessary to start a clinical study. The process may begin at two different points. Specifically, if the sponsor wishes to begin by making a feasibility assessment with respect to the study, the process starts at step 804. Alternatively, if the sponsor does not wish to make a feasibility assessment, the process starts at step 811.

In step 804, the sponsor enters various criteria necessary to identify potential subjects and/or investigators for the study into the system. These criteria include, for example, criteria that determine which subjects may be included or excluded from the study, one or more specialties that an investigator for the study should have, information about the prescribing behavior of the investigator, the number of studies that the investigator should have conducted, the therapeutic area and disease indication associated with the clinical study, the distance around the investigator site in which subjects participating in the study should be found, and the geographic area in which the investigator should be found.

Next, in steps 806, 807 and 808, various criteria from step 804 are applied to the TIA, subjects and investigator databases in order to assess the likelihood that sufficient subjects will be available for the study, and to assess the likelihood that a sufficient number of suitable investigators will be available for the study. In applying the subject criteria to both the TIA and subject database, the present invention is able to both identify subjects in the subject database that may be appropriate for the clinical study (this information comes from the subject database), and also identify geographic areas where incidences of the relevant diseases or conditions are more prevalent (this information comes from the TIA database.) By querying the TIA database for this disease incidence/prevalence information, the system is able to identify geographic areas where potential subjects (not listed in subject database) may be more likely to be found using off-line and/or on-line recruiting not involving the subject database. In addition, the geographic locations of investigators who may qualify for the study are compared against the TIA search results and the search results from the subject database (specifically, the locations of such subjects) in order to identify investigators with the highest likelihood of fulfilling the enrollment requirements of the study because they are located proximate to where there are the largest numbers of suitable subjects. This aspect of the assessment process recognizes that, in the case of some studies, potential subjects may be unwilling to travel any significant distance to participate in the study, while, for other studies, potential subjects may be prepared to travel great distances. Therefore, even if an investigator is otherwise qualified to perform the study, if sufficient subjects are not located proximate to the investigator's site, it may be more challenging for the investigator to fulfill the subject recruitment required for the study. By correlating the geographic location of suitable subjects from the subject database and locations having a relatively higher incidence or prevalence of the disease associated with the study (from the TIA

database) to the locations of suitable investigators listed in the investigator database, the present invention is able to locate investigators who are not only qualified, but also proximate to large numbers of subjects, and thus have the greatest likelihood of fulfilling the sponsor's expectations with respect to both enrollment and quality of performance.

Following the review of the search results from steps 806, 807 and 808, the sponsor makes a subjective assessment in step 810 as to the feasibility of the study based on the results obtained from the TIA, subject and investigator databases. In this step, the sponsor determines whether there is a sufficiently large pool of potential subjects who are close enough geographically to a potential investigator to make the study feasible. If, in step 810, the sponsor concludes that it would not be feasible to recruit sufficient suitable subjects and/or investigators for the study, the sponsor is given an opportunity to revise the subject and investigator criteria entered in step 804 in an effort to arrive at a feasible study. In accordance with this aspect, the sponsor repeats the process described above using revised subject and investigator criteria until the sponsor finds a study for which subject and investigator recruitment appears feasible.

The sponsor reaches step 811 either as an entry point into the process, or after the sponsor has determined in step 810 that the study is feasible. In step 811, the sponsor determines whether the sponsor desires to use the investigator database to perform investigator recruitment for the study. If the sponsor wishes to use the investigator database for investigator recruitment, then in step 815, the sponsor begins by entering study parameter information into the system. A screen shot of a web page that may be used for entering this information is shown in Figure 9. In this step, the sponsor enters various parameters about the study into the system. Next, in step 816, the sponsor enters investigator search criteria for the study into the system. Such search criteria could include, for example, one or more specialties that would be desirable for an

investigator for the study, information about the prescribing behavior of the investigator, the number of studies that the investigator has conducted, the therapeutic area and disease indication associated with clinical studies previously conducted by the investigator, the distance around the investigator site in which subjects participating in the study should be sought, and the geographic area in which the investigator should be located. Figure 10 is a screen shot of an exemplary web page that may be used by a sponsor to input the investigator search criteria into the system. In step 818, the sponsor is given the ability to weight one or more of the investigator criteria prior to initiating the investigator search.

In step 820, the investigator criteria and any weight applied by the sponsor, are applied to the investigator database in order to identify potential investigators for the clinical study. In one embodiment, results from queries to the TIA and subject databases for the study are also incorporated into the investigator selection process. By correlating the geographic location of suitable subjects from the subject database and locations having a relatively higher incidence or prevalence of the disease associated with the study (from the TIA database) to the locations of suitable investigators listed in the investigator database, the present invention is able to identify in step 820 investigators who are not only qualified, but also proximate to where potential subjects with the relevant disease live or are willing to travel.

An exemplary web page that shows the results of an investigator search in accordance with the present invention is shown in Fig. 11. As shown in that figure, for each investigator identified in the search, the sponsor is shown the name of the investigator, the investigator's specialty, the city/state in which the investigator is located, the number of studies that the investigator has performed, subject demographic information obtained from the TIA database (i.e. the number of persons listed in the TIA database that are within a predetermined distance of



the investigator site and who could potentially qualify as subjects for the clinical study), subject demographic information obtained from the subject database (i.e. the number of subjects listed in the subject database that are within a predetermined distance of the investigator site and who could potentially qualify to participate in the clinical study), the drug prescribing behavior of the investigator (e.g., the drug class prescribing decile associated with the investigator). It will be understood by those skilled in the art that other criteria relevant to the investigator could also be shown on this search results screen including for example, the behavior of the investigator with respect to ordering of laboratory tests/procedures.

In step 822, the sponsor selects one or more investigators for the clinical study, and in step 823 begins the process of engaging the investigator(s) for the study. As mentioned above, this process is accomplished using a secure extranet embodied by the professional site. This extranet preferably includes document templates that allow sponsors (and/or investigators) to quickly generate documents relevant to the launch of a clinical study. These documents include for example, an initial questionnaire that a sponsor may send a potential investigator in order to more fully assess whether or not the investigator would be appropriate to conduct the clinical study. Other documents that may need to be in place before the study is started include a confidentiality agreement between the sponsor and investigator, and a synopsis of the study to be completed. These documents are preferably created using standard templates found in the workspace on the professional site associated with each sponsor or investigator. These documents are also preferably exchanged between the sponsor and investigator only within the extranet thereby insuring that confidentiality of such documents is securely maintained and tracked, and allowing separate version control for each of multiple investigators being recruited for the same study. Figures 12 and 13 are screen shots of web pages from the professional site

showing use of the extranet for the creation and tracking of documents necessary for the start of a clinical study. The failure to complete or provide any of the documents required to start the study may be fatal to the investigator recruitment process, and may require repetition of the process (from either step 816 or 822) until the investigator recruitment process can be completed.

After step 823, the sponsor decides whether the sponsor is interested in using the subject database to identify potential subjects for the study. If the sponsor is interested in using on-line and/or off-line patient recruitment and retention services, then in step 817 a combination of on-line recruitment and off-line recruitment is used to identify potential subjects for the study. In the on-line recruitment process, the sponsor enters various criteria necessary to identify potential subjects for the study into the system. These criteria include, for example, the inclusion/exclusion criteria of subjects for the study, the therapeutic area and disease indication associated with the clinical area, and/or the distance around the investigator site in which subjects participating in the study should be found. The subject criteria are then applied to the subject database, in order to identify on-line potential subjects for the study.

Off-line recruitment is used for identification of potential subjects either by itself (step 819) or in combination with on-line recruiting techniques (step 817). Off-line recruiting is how most participants for clinical studies are currently recruited in prior art systems, and this method involves making contact through media with a potential subject in order to attempt to recruit the subject for a given clinical study. In performing off-line recruiting, the sponsor may optionally use results from a search of the TIA database to assist in identifying a geographic area where subjects for study are more likely to be found.

After a potential subject has been identified (step 817 or 819), the process of pre-screening for participation in the study begins (step 824). In this step, subjects identified using

on-line and/or off-line recruitment are notified, and asked whether or not they have an interest in participating in the clinical study. In the case of candidates that were identified on-line using the subject database, the subjects are preferably contacted by the means that they identified during their registration on the subject site (e.g., by electronic mail) in order to preliminarily determine whether they have an interest in participating in the clinical study. A screen shot of an exemplary e-mail used for providing such a notification to a potential subject is shown in Fig. 14. The notification could alternatively be provided using telephone, mail, fax or any off-line communication means. If a potential subject responds to a notification by indicating interest in participating in a clinical study, the subject is provided with a formal questionnaire that asks for information specifically relevant to the clinical study. An exemplary study-specific subject questionnaire is shown in reference to Figs. 15A – 15F. In the preferred embodiment, if in response to the e-mail notification shown in Fig. 14, the subject indicates interest in participating in the clinical study, a study-specific subject questionnaire such as shown in Figs. 15A – 15F is provided to the subject on a secure web page found on the subject site. The subject then uses this secure web page to answer all of the questions in the subject questionnaire, and to submit such answers for consideration. As mentioned above, irrespective of whether the subject is ultimately selected for participation in the clinical study, these questionnaire answers are stored in the subject database with the consent of the patient, thereby enriching the subject information stored in that database.

Following the pre-screening process described above, a list of pre-screened subjects who may be eligible to participate in a clinical study is given to the investigator. Next, in step 826, the investigator schedules an appointment with each of the subjects on his or her pre-screened list. The subject gets examined and signs an informed consent before the investigator can enroll

the subject in a study. In step 830, allocation numbers for each of the subjects selected by the investigator for the clinical study are provided to the sponsor. Since the sponsor must be blind to the identities of the subjects participating in the study, the sponsor is provided with only allocation numbers of the subjects, and no identifying information (such as the name or address of such individuals) is provided to the sponsor.

Finally, in step 832, information about each of the subjects participating in the study is provided electronically from system 100 to an electronic data capture ("EDC") company. EDCs are typically used during the performance of a study to store and capture data from investigator(s). By electronically providing information about each of the subjects in the study to the EDC prior to start of the clinical study, the present invention facilitates the set-up of the EDC database prior to the start of a clinical study. In one embodiment, the present invention includes several different data conversion templates, each of which converts subject data (from the subject database) to a format associated with a given EDC, prior to transmission of any subject data to such EDC.

In some embodiments, the inventive system may be linked to the systems of other entities involved in the clinical studies process, thereby creating an automated clinical studies system from compound development through study feasibility and subject/investigator recruitment, study conduct and post-study marketing.

The sponsor may use the inventive system to identify both investigators and subjects, may have engaged an investigator and simply be recruiting subjects, may be looking for an investigator to take over an ongoing study, or may be looking for an investigator who will then recruit subjects.

### **Specific Investigator Identification Embodiments**

Fig. 16 is a process flow diagram of a method for identifying eligible investigators for a clinical study in accordance with one embodiment of the present invention. Specifically, at step 1610, information is stored in database 2200 of the inventive system (in particular, the data is stored in table 2252, field 2252a of Fig. 22B) relating to the geographic location of each of a plurality of investigators. At step 1620, an incidence or a prevalence of each of a plurality of disease conditions in a plurality of different geographic locations is stored in the database.

At step 1630 the system queries the database for a selected disease condition associated with the clinical study at issue. The query results in a list of locations wherein there is a relatively greater incidence or prevalence of the selected disease condition. From the result of this query, the system identifies both investigators that may qualify to perform the clinical study based upon the geographic location of the investigator compared with the query result, as shown at step 1640, and potential registered subjects. Thus, an investigator located where there is a requisite incidence or prevalence of the selected disease condition is potentially eligible.

Fig. 17 is a process flow diagram showing the steps of a method for identifying eligible investigators for a clinical study in accordance with another embodiment of the present invention. At step 1710, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding the prescription writing history of each of the investigators with respect to a plurality of classes of medications. The prescription writing history information is provided by a third party.

At step 1720, information is stored in the database that associates each of the plurality of medications discussed above with one or more disease conditions. At step 1730, the database is queried wherein information representing a selected disease condition associated with the

specific clinical study is used. The query will result in correlation between the specific disease condition and related prescriptions. At step 1740 the inventive system identifies an investigator based upon the query results and the investigator's prescription writing history. The determination may be based, for example, upon the volume of prescriptions for the medications written by the investigator as compared to the volume of prescriptions for that medication written by other physicians. The determination may vary depending upon the specific clinical study, and will be known to those skilled in the art and is within the scope of the present invention.

Fig. 18 is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet another embodiment of the present invention. At step 1810, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding the history of each investigator's request for laboratory procedures (e.g., blood work for subjects, urinalysis, EKG, etc.). Other requests will be known to those skilled in the art and are within the scope of the present invention.

At step 1820, information is stored in the database that associates each of the laboratory procedure requests discussed above with one or more disease conditions. At step 1830, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related laboratory procedures. At step 1840 the inventive system identifies an investigator based upon the query results and the investigator's laboratory procedure requests. The determination may be based upon the fact that the investigator has never requested a certain laboratory procedure, or always prescribes a certain laboratory procedure. The determination

may vary depending upon the specific clinical study, and will be known to those skilled in the art and is within the scope of the present invention.

Fig. 19 is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study, in accordance with yet a further embodiment of the present invention. With reference to Fig. 19, in step 1910, information regarding a plurality of investigators is stored in a database. Such information includes the history of each investigator's past participation in clinical studies. The history information is stored in a database of the inventive system (shown at table 2220, field 2220A of Fig. 22A). In step 1920, the database is queried using criteria about past clinical study participation. In step 1930, a qualified investigator for a clinical study is identified based on the results of the query regarding past clinical study participation.

Fig. 21A is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study, in accordance with a further embodiment of the present invention. With reference to Fig. 21A, in step 2101, information regarding a plurality of investigators is stored in a database. Such information includes a geographic location of subjects located near the investigator. In step 2102, the database is queried using criteria about a selected disease condition. In step 2103, a qualified investigator for a clinical study is identified based on the results of the query and the geographic location of the investigator's subjects.

Fig. 21B is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with another embodiment of the present invention. At step 2104, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding

the investigator's medical specialty, which can be supplied either by the investigator or a third party, such as a certification board.

At step 2105, information is stored in the database that associates each of the investigator's specialty with one or more disease conditions. At step 2106, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related specialties. At step 2107 the inventive system identifies an investigator based upon the query results and the investigator's specialty.

Fig. 21C is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet another embodiment of the present invention. At step 2108, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding the experience of an investigator's medical staff, which may include the actual size of the staff, any particular expertise among the staff, etc. Other information about an investigator's staff will be known to those skilled in the art and are within the scope of the present invention. The staff information can be supplied by the investigators or third parties.

At step 2109, information is stored in the database that associates the experience of the investigator's medical staff discussed above with one or more disease conditions. At step 2109, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related staff experience. At step 2110 the inventive system identifies an investigator based upon the query results and the experience of the investigator's medical staff.



Fig 21D is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with another embodiment of the present invention. At step 2112, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the number of clinical studies each investigator has performed. This number can be supplied by the investigators or third parties.

At step 2114, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. At step 2115 the inventive system identifies an investigator based upon the query results and the number of investigator clinical studies.

Fig. 21E is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet another embodiment of the present invention. At step 2116, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes hospitals with which the investigator is affiliated. This information can be supplied by the investigators or third parties.

At step 2117, information is stored in the database that associates each of the investigator hospital affiliates with one or more disease conditions. At step 2118, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. At step 2119 the inventive system identifies an investigator based upon the query results and the investigator's hospital affiliates.

Fig. 21F is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with a further embodiment of the present invention. At step 2120, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes each of the

investigator's hospital affiliates' number of beds, which may include information regarding how many beds are dedicated to ICU, cancer, OBGYN, etc. The information can be supplied by the investigators or third parties.

At step 2121, the number of hospital beds is associated with one or more disease conditions. At step 2122, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. At step 2123 the inventive system identifies an investigator based upon the query results and the number of beds in an investigator's affiliated hospitals.

Fig. 21G is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet a further embodiment of the present invention. At step 2124, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding each investigator's insurance provider affiliations. The insurance provider affiliation information can be supplied by the investigators or third parties.

At step 2125, information is stored in the database that associates each of the insurance providers with one or more disease conditions. At step 2126, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related insurance providers. At step 2127 the inventive system identifies an investigator based upon the query results and the investigator's insurance provider affiliations.

Fig. 21H is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet a further embodiment of the present invention. At step 2128, information is stored in the inventive system database relating to

prospective investigators for clinical studies. This information includes information regarding each investigator's mandated IRB relationships. For example, an investigator may be affiliated with a local IRB or central IRB. The mandated IRB relationships information can be supplied by the investigators or third parties.

At step 2129, information is stored in the database that associates each of the investigators with IRBs. At step 2131 the inventive system identifies an investigator based upon the query results and the investigator's mandated IRB relationships.

Fig. 21I is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet a further embodiment of the present invention. At step 2132, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes regulatory agency audits that have been performed for each investigator. This information may include audits from the FDA, or other audits that are known to those skilled in the art. The audit information can be supplied by the investigators or third parties.

At step 2133, information is stored in the database that associates each of the regulatory audits with one or more disease conditions. At step 2134, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related audits. At step 2135 the inventive system identifies an investigator based upon the query results and the agency audits of the investigator.

Fig. 21J is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with an additional embodiment of the present invention. At step 2136, information is stored in the inventive system database relating to

prospective investigators for clinical studies, which includes the investigator's PRF affiliations. This information can be supplied by the investigators or third parties.

At step 2137, information is stored in the database that associates each of the investigators with particular PRFs as appropriate. At step 2138, the database is queried. At step 2139 the inventive system identifies an investigator based upon the query results and the investigator's PRF affiliations.

Fig. 21K is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet an additional embodiment of the present invention. At step 2140, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding each investigator's medical equipment, such as is the investigator has a CAT scanner, and EKG machine, etc. The information can be supplied by the investigators or third parties.

At step 2140, information is stored in the database that associates the types of equipment that an investigator has with one or more disease conditions. At step 2141, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related equipment that an investigator has. At step 2142 the inventive system identifies an investigator based upon the query results and the investigator's equipment.

Fig. 21L is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet a further embodiment of the present invention. At step 2143, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the investigator practice setting,

which is where the actual clinical study is conducted, and where a subject would most likely go to participate. This information is provided by the investigator.

At step 2144, information is stored in the database that associates the investigator practice setting with one or more disease conditions. At step 2145, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related setting information. At step 2146 the inventive system identifies an investigator based upon the query results and the investigator's practice setting.

Fig. 21M is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with another embodiment of the present invention. At step 2147, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the investigator's city and state. This information is provided by the investigator.

At step 2148, information is stored in the database that associates each of the investigator's city and state. At step 2149, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and the investigator's city and state. At step 2150 the inventive system identifies an investigator based upon the query results and the investigator's city and state.

Fig. 21N is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with another embodiment of the present invention. At step 2151, information is stored in the inventive system database relating to

prospective investigators for clinical studies, which includes the investigator's name. This information is provided by the investigator.

At step 2152, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. At step 2153 the inventive system identifies an investigator based upon the query results and the investigator's name.

Fig. 21O is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet another embodiment of the present invention. At step 2154, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding the history of each investigator's laboratory results. The laboratory results information can be supplied by the investigators or third parties.

At step 2155, information is stored in the database that associates each of the laboratory results discussed above with one or more disease conditions. At step 2156, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related laboratory results. At step 2157 the inventive system identifies an investigator based upon the query results and the investigator's laboratory results. The determination may vary depending upon the specific clinical study, and will be known to those skilled in the art and is within the scope of the present invention.

Fig. 21P is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with a further embodiment of the present invention. At step 2158 information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes, with respect to each

hospital with which the investigator is affiliated, the services performed, which may include information regarding whether the hospital performs transplants, dialysis, burn units, etc. The information can be supplied by the investigators or third parties.

At step 2159, the services performed are associated with one or more disease conditions. At step 2160, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. At step 2161 the inventive system identifies an investigator based upon the query results and the number of beds in an investigator's affiliated hospitals.

Fig. 21Q is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with an additional embodiment of the present invention. At step 2162, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the investigator's hospital claim information. This information pertains to claims made by subjects to a hospital, which claims include disease condition information and also are associated with an investigator. Such information can be supplied by the investigators or third parties.

At step 2163, information is stored in the database that associates each of the claims with one or more disease conditions. At step 2164, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related claims. At step 2165 the inventive system identifies an investigator based upon the query results and the claims.

The investigator database may also include any combination of, or all of the above information related to the investigator. Moreover, the query of the investigator database may

further include search criteria selected from any, and/or all, and all combinations of the information stored in the database. Therefore, the query may include any permutation of combinations of the information including the investigator's prescription writing history, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to the medical specialty of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, and information corresponding to the investigator's name.

### **Investigator Ranking System**

In selecting an investigator for a particular study, in some embodiments, a sponsor may employ an investigator ranking system which is a tool to help predict the success of an investigator in performing clinical studies. In this embodiment, certain fields of the investigator database (as discussed in more detail below with reference to Fig. 21) are weighted based on one or more algorithms and an investigator is assigned a ranking value. Some of the fields of the investigator database that may be used are as follows: reported study performance by sponsors; reported study performance by third party sources; 1572 counts from the FDA; FDA audit lists;



hospital affiliation; mandated IRB relationships; drug prescribing decile for related classes of drugs; aggregate subject demographics of disease incidence proximate to investigator location; and self-reported data. The weighting algorithm is derived using the investigator's past clinical study experience as a basis. The specific weighting algorithm can be used as a tool to predict performance by an investigator on studies for drugs in a variety of specialties.

Thus, for example, in one embodiment, the fields selected for weighting are as follows: investigator experience (namely, the number of 1572s filed in the last five years); the professional certification (namely, if the investigator is board certified, the number 1 is assigned and if not, a zero value is assigned); scientific leadership (namely, the total number of peer-reviewed publications in the past five years); regulatory criteria (namely, for any FDA audits conducted in the past five years, assigning the number 1 if no warning letter was issued, assigning a zero value if no audits were conducted, and assigning a -1 if a warning letter was issued); and study coordinator criteria (namely, the total number of study coordinators ACRP certified). The value for investigator experience is weighted by multiplying it by 1; the value for professional certification is weighted by multiplying it by 5; the value for the specific leadership is weighted by multiplying it by 5; the value for the regulatory criteria is weighted by multiplying it by 25; and the value of study coordinator criteria is weighted by multiplying it by 5.

In some embodiments, the inventive system refines these rankings by later analysis of clinical study results.

### **Subject Recruitment**

Fig. 20 is a process flow diagram showing the steps of a method for recruiting a person to participate in a clinical study in accordance with one embodiment of the present invention. As

shown in step 2010 of Fig. 20, a person is presented with one or more web pages sponsored by the inventive system, as discussed above and shown in Figs. 2A and 2B. The person may be the subject himself or herself or a caregiver of the subject. The caregiver may be either the legal guardian of the subject, or a friend or relative or other interested person. The web page(s) has a registration form that requests a variety of information from the person. For example, the form may ask for the geographic location of the person, which may include a specific city in which the person resides and the distance the person is willing to travel to participate in a clinical study (with reference to Fig. 3). The registration form also may ask for the gender and age of the person, at least one disease condition of interest to the person, a medical history of the person and/or numerous other factors known to those skilled in the art. The form also may include contact information, such as a relative or friend who may be contacted in an emergency. Other registration information will be known to those skilled in the art and are within the scope of the present invention.

Further, the form may inquire as to consent information about the person. This information includes queries about the person's date of birth. The form may also inquire as to whether the person wishes to receive notice of one or more clinical studies and permission to send the same. The clinical study information sent may be targeted specifically to the person's disease condition of interest, may be targeted to pharmaceutical histories, geographic location, etc.

At step 2020 of Fig. 20, the person, or caregiver, completes the registration form as presented on the web page(s). The data is submitted to the subject database and stored therein as described later with reference to Fig. 24, shown as Tables 2410 and 2420. Once the database is

populated with the registration information, the person or caregiver is automatically registered with the inventive system, as shown in step 2030.

Once the person or caregiver is registered, the inventive system evaluates the information provided in the registration form and determines if the person or caregiver should receive notice of a clinical study, as shown in step 2040. For example, the inventive system asks the person or caregiver to confirm that he or she is legally qualified to provide simple consent to add the person's information to the database and to give permission to receive notices about clinical studies. This determination may be based upon information of the person's age, or whether the person or caregiver actually gave permission to receive such notices, for example.

The system also evaluates the information with respect to the person's possible selection for a clinical study. For example, the system queries the database based on: a disease condition of interest indicated by the subject; the geographic location of the subject; other information from the registration of the subject or a prior questionnaire completed by the subject; and the geographic location of the investigator that has been selected to perform the clinical study. Other determining factors will be known to those skilled in the art and are within the scope of the present invention.

If the system determines that the person does not match the geographic location and disease condition of any currently available clinical studies, the inquiry about the person ends. In some embodiments, the system asks the person if the system may contact the person about future studies that may match the criteria set forth in the registration by the person. If, so, when a new study is entered, the person may show up as a potentially eligible subject, and an e-mail or other notification will be delivered to the person. If, on the other hand, the data regarding the person matches data related to a clinical study, the system provides the person or caregiver with

notification of the clinical study, as shown as step 2050. This notification may be by e-mail, telephone or regular mail, as desired by the person, for example with reference to Fig. 3.

Once a person is notified of a clinical study that may be of interest, the system presents to the person a questionnaire that is specifically associated with the clinical study at step 2060. In some embodiments, the person will receive an electronic mail or other notification that a study may match their needs, and the person initiates contact with the system or with a call center to take the particular pre-screening questionnaire. This questionnaire requests information about the person regarding high level inclusion/exclusion criteria. The answers given by the person or caregiver to the questionnaire are securely stored in the subject database of the system (Fig. 24) at step 2070.

As discussed above, this information is evaluated and the person is pre-screened for a clinical study. If the person's responses to the pre-screening indicate that the person may be eligible to participate in the study, the person will be given an investigator name and address and contact information where the subject can schedule an appointment to undergo a more detailed screening process to determine whether the person is qualified to participate. Should the person not be chosen, the information previously stored in the subject database from the questionnaire is evaluated to determine if the person is qualified to participate in a different clinical study than that previously matched, as shown in step 2080. As with the previous determination made, typical queries include whether the person is within a geographic location (as defined by the person or caregiver) of another clinical study and if the person has a disease condition of interest that corresponds with another clinical study. Other determining factors will be known to those skilled in the art and are within the scope of the present invention.

If it is determined that the person is qualified to participate in a different clinical study, the system provides the person with notice of that clinical study, as was discussed earlier. If the subject is eligible for two studies, the subject is presented with them both simultaneously.

### **Push Technology For Enrolling Participants**

As an alternative to a passive method of enrolling investigators, sponsors, and clinical subjects, push technologies can be used to deliver descriptions of the service and to enroll participants. The subject database accommodates this type of data. Using suitable methods of privacy protection, information can be emailed to unregistered individuals to notify them of the potential to participate in an ongoing study. Similarly, location or ease of access may be important in designing or implementing a study. The GPS functionalities built into wireless phones and other communications devices combined with the ability to transmit information, such as that provided by Bluetooth wireless technology would permit sponsors or investigators to directly contact individuals within particular locations.

### **Selection of Subjects Using Genotype and Phenotype Data**

In addition, the present invention permits more efficient use of genotype as well as phenotype data, and other genetic sequencing information, for better selection of candidates for clinical studies. Thus, medical practitioners, including but not limited to doctors, nurses, blood banks, pharmacists, etc., take blood, tissue scrapings or hair samples for genetic analysis to determine the presence of various alleles and polymorphisms. Such samples are analyzed for the presence of various alleles that might correlate or be associated with various diseases. This polymorphism analysis is greatly improved by such techniques as the DNA chip. Such chips are manufactured by a number of different sources such as Affymetrix, Santa Clara, California.

Alleles that are associated with metabolic polymorphisms can also be identified. This is of great importance if differing breakdown rates or even products of the investigational compound affect the drug's safety or efficacy. In this manner, a sponsor can begin clinical studies on a more homogenous population to simplify the complexities of the testing process. Indeed, such a discrete portion of the population can, in some cases, arguably qualify for special testing parameters, such as that for an Orphan Drug. After approval of the product for such subpopulations, testing is continued to obtain regulatory approval of the product for the population at large.

Many forms of disease appear to be genetically linked including, for example, early onset breast cancer. In early onset breast cancer, the presence of certain gene sequences such as the BRCA-1 mutation greatly increase the probability that the disease will occur. In many cases, the presence of the BRCA-1 mutation does not lead to the disease, and the disease also can occur when the BRCA-1 mutation is not present. For a product associated with breast cancer, clinical study sponsors may wish to first test their product on discrete populations – such as those with the BRCA mutation – to determine if such a discrete population reacts differently to a product compared to the population at large. Most importantly, testing such differing populations can lead to greater safety and efficacy in new drug products for the subpopulations tested. Moreover, identification of differences in response is important in discovering improved drugs. Alternately, the product may be designed only for use by a discrete population, such as that with a particular disease and a particular genotype.

In the alternative, the sponsor might wish to garner a more heterogeneous population for testing. Moreover, as genomic research advances, regulatory agencies might require studies that

specifically target a large number of different alleles to obtain market approval for the entire population.

This ability to pool test subjects, either individually or as parts of large groups such as could be assembled by blood banks and laboratory testing companies, permits easier marketing of genomic information and stimulates research in this area. The site of the present invention has the ability to act as a clearinghouse to match potential sponsors with groups or individuals that, for example, have particular genotypes and phenotypes. Indeed, as the cost of genomic testing goes down, the invention may be a centralized location that potential clinical subjects may contact not only for participation in studies, but for background genetic tests. As those of ordinary skill in the art will recognize, the present invention may include genetic sequence information in any of the databases described herein. Moreover, any of the functionality described herein which is based on or operates on disease condition, medical, or treatment information may also be based on or operate on genetic sequence information.

Investigators, persons or other parties supply genetic sequence information for inclusion in the subject database and/or the TIA database along with other suppliers of clinical subjects post the potential clinical subjects that they have identified by location, genetic background at particular genetic loci, family history, lifestyle or any other criteria and then market access to these subjects to potential sponsors. In this way, the invention stimulates the ease of access to unique subject populations.

The invention also permits more efficient marketing of pharmaceutical products and post-marketing studies. The invention collects and pools information regarding the locations of particular doctors as well as their prescription habits. Such information can be used in the design

of post-marketing studies as well as determining which doctors would be most easily approached to sell different drug formulations.

### **Building the Investigator Database**

As described earlier, prospective investigators enter data into the Investigator Questionnaire (Fig. 7 described above) that includes information regarding the investigator's professional background and information about past clinical studies performed by that investigator. In other embodiments, known to those skilled in the art, data relating to the investigator is provided by the investigator not by way of a web site, but orally or by off-line written means.

Specifically focusing on the information regarding past clinical studies, the investigator is asked for data relating to the specific types of clinical studies the investigator performed in the past, the class of drugs that were tested, the protocol number, what recruiting commitments were made by the investigator in each of the past clinical studies, how successful the investigator was in meeting the recruiting commitments, how many subjects participated in the study, and of those who began the study, how many actually completed the study. This data is stored in the database 2200 as shown in Fig. 22. For example, the investigator may have committed to recruiting 25 subjects over a six-month period of time for a particular clinical study. The database will thus include information about this commitment and results therefrom, *i.e.* was the investigator successful in meeting this commitment, how many subjects actually participated in the study, and of those subjects who began the study, how many actually completed the study (clinically evaluable subjects).

The investigator database also includes information regarding the investigator's publications in the related medical fields, the number of subjects the investigator treats in a given



time-frame, any specialties the investigator may have, what board certifications the investigator has, what types of equipment are available to the investigator, affiliated hospitals, the size and expertise of the investigator's staff, etc. Other types of data relating to the investigator will be known to those skilled in the art and are within the scope of the present invention.

Third party information may be used to validate self-reported information submitted by an investigator. Such third party information may include data received from the FDA through the Freedom of Information Act ("FOIA"). In particular, for every clinical study performed in the United States an investigator must submit to the FDA a Form 1572 or appropriate analog. The non-confidential information of Form 1572 can be obtained through FOIA, and includes, for example, the names and addresses of all of the investigators who conducted a particular clinical study. The FDA also performs audits on clinical studies, which can result in a Form 483. Again, all non-confidential information from the 483 audit can be obtained through FOIA. Validated data also is obtained from various other third parties such as entities that collect performance data as a result of the conduct of their own businesses.

Fig. 22A through 22F is an exemplary data structure for implementing an investigator database 2200. For example, table 2210 includes investigator data related to basics such as name, age, address, phone, etc. Table 2220 contains data about a specific study performed by the investigator, Table 2230 relates to the investigator's specialties, and Table 2240 relates to the investigator's subject population. Shown in Fig. 22B, table 2250 contains data about the investigator's staff. Table 2260 of Fig. 22C contains data regarding the investigator's hospital affiliations. It will be understood by those skilled in the art that the investigator database of the present invention could be implemented using many different formats or structures, and that the

particular structure shown in Figs. 22A thorough 22F represents one example of such a data structure.

**Example: Use of TIA Database To Assist in Investigator and Subject Selection**

Figs. 22G-K depict use of a disease incidence search on a TIA database to assist in performing investigator and subject selection. The example shown relates specifically to use of the invention to perform a study related to the disease of angina. Initially, the TIA database is queried using angina as the query criterion to identify geographic locations where the incidence of angina is more prevalent. These areas are identified on a national basis in Fig. 22G, and specifically for the Dallas-Fort Worth area in Fig. 22H. It bears noting that, within the Dallas-Forth area, the TIA database has further identified an incidence value for each sub-region of the Dallas-Fort Worth area. Sites of various investigators in Dallas-Fort Worth that are potentially eligible to perform the study are also shown on Fig. 22H. These investigator sites were found by querying the investigator database as described above. Fig. 22I shows that there are three eligible investigator sites in the Dallas-Fort Worth Area. These three investigator sites are shown as circled stars in Fig. 22I. Of the three eligible investigator sites, one of the investigator sites is located in a sub-region having a higher incidence of angina than is found in the sub-regions of the other two eligible investigators. As shown in Fig. 22J, the investigator located in the sub-region having the highest incidence of angina is next selected to perform the study. Following selection of this investigator for the study, subjects closest to the site of the selected investigator are identified for screening, as shown in Fig. 22K.

**Sponsor Data Access Limitations**

A sponsor who has submitted data for inclusion in the investigator database must be afforded appropriate confidentiality protections to ensure their continued competitive advantage.

Thus, in one embodiment of the present invention, the inventive system provides limited access views of such data. This method maintains the confidentiality of clinical study information associated with number of clinical study sponsors. In connection with this method, the clinical study information from the sponsors is received and stored in a database. Each sponsor is permitted full access to the clinical study information submitted by that sponsor and only aggregated access to information submitted by other sponsors. The clinical study information includes, in one embodiment, investigator information, sponsor identification, protocol information, drug indication information, drug class information, clinical study enrollment goal information, actual clinical study enrollment information, and clinically evaluable subjects information. In one embodiment, each sponsor is denied access to the protocol information, drug class information and sponsor identification information of other sponsors.

Fig. 23 is a screen shot showing sponsor access limitations to study data. Aggregated data 2302 can be viewed by all sponsors, whereas data 2304 can only be viewed by the sponsor that supplied that data 2304 to the database. Fig. 26 depicts an exemplary data structure used for implementing the sponsor access limitations discussed above.

#### **Multi-Viewer Content Presentation**

The subject site the inventive system includes content such as, e.g. new articles, feature stories, drug listings, expert Q&A transcripts, etc., from multiple different sources for presentation to potential subjects and other persons visiting the subject site. The content as provided by the source is provided using verbiage which is highly technical and sophisticated. However, the content is transformed and presented to visitors of the subject site in a manner which is lay-accessible. Similarly, content which is collected from various sources for

presentation on the professional site is transformed and presented in a manner which is appropriate for individuals accessing the professional site, such as investigators and sponsors.

#### **Certification of Investigators**

The professional site may include, in some embodiments, a toolkit presented to investigators which includes training materials for investigators, including training regarding appropriate practices for clinical research on humans. Continuing medical education credits may be awarded to investigators completing a specified amount of training.

#### **Permission Based Electronic Mail Marketing**

The systems and methods of the present invention can be utilized for the marketing of FDA approved new drugs and devices. Fig. 27 is a flow diagram of a method for performing permission-based electronic mail marketing to consumers, in accordance with the present invention. In steps 2710-2720, one or more web pages are presented that allow a person to register with the subject database by submitting registration and permission information to the database. The registration information includes name information and contact information and the permission information indicates whether the person wishes to receive notice of one or more clinical studies. In step 2730, the person is automatically registered with the database upon receipt of the registration and permission information. In step 2740, permission is obtained to send marketing information concerning drugs, medical devices or medical therapies to the person. The database is added to in step 2750 by repeating the above steps for a plurality of persons. Next, in step 2760 a list is generated for use in marketing drugs, medical devices and medical therapies to subjects by querying the database using criteria associated with the drugs, medical devices and medical therapies. Optionally, the system also automatically determines, in

accordance with the registration and permission information, whether to provide the person with notice of a clinical study associated with a disease condition of interest to the person.

### **Optimization of Recruiting Methodology**

As the inventive system collects an ever-increasing amount of data regarding clinical investigators (and, in particular, the best performing clinical investigators), highly effective methods of recruiting clinical study subjects, who are clinically evaluable, may be identified by studying the methods employed by the best performing clinical investigators. Thus, the inventive system will allow for the identification of the clinical investigator recruiting techniques that result in the highest enrollment rates and number of clinically evaluable subjects.

Similarly, as the inventive system collects an ever-increasing amount of data regarding clinical subjects (and, in particular, those who become evaluable), highly effective methods of recruiting subjects, who are most likely to become evaluable, may be identified. Thus, the inventive system will allow for the identification of the clinical subject recruiting techniques that result in the highest enrollment rates and number of clinically evaluable subjects.

### **Remaining Database Structures**

Figs. 24A through 24D depict an exemplary data structure for implementing a subject database 2400. Again, it will be understood by those skilled in the art that the subject database of the present invention could be implemented using many different formats or structures, and that the particular structure shown in Figs. 24A through 24D represents one example of such a data structure. In addition to storing information inputted by the subject as discussed with reference to Figs. 2 through 6, database 2400 may store the criteria used by a potential clinical subject to search for a particular clinical study. The search criteria selected may be used to provide additional insight into the tendencies and/or interests of a potential clinical subject.

Fig. 25 depicts an exemplary data structure for implementing a study database 2500. Again, it will be understood by those skilled in the art that the subject database of the present invention could be implemented using many different formats or structures, and that the particular structure shown in Fig. 25 represents one example of such a data structure.

While the description herein refers to the information existing in multiple databases, those of ordinary skill in the art will recognize and understand that all such information could be stored in a single database or in several databases structured differently than those described herein.

It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but is intended to cover modifications within the spirit and scope of the present invention as defined in the appended claims.

What is claimed is:

1. A method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:

(a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database, wherein the registration information includes at least a geographic location of the person, at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies;

(b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information;

(c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person; and

(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice.

2. The method of claim 1, further comprising the steps of:

(e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and

(f) storing answers submitted by the person or caregiver in the database.

3. The method of claim 2, further comprising the step of :

(g) accessing the information stored along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f).

4. The method of claim 1, wherein the questionnaire includes criteria specified by a sponsor of the clinical study for determining whether the person is an eligible subject for the given clinical study.
5. The method of claim 1, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (d) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site.
6. The method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site.
7. The method of claim 1, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver.
8. The method of claim 1, wherein the notice provided in step (d) is sent by regular mail to the person or caregiver.



9. The method of claim 1, wherein the notice provided in step (d) is communicated by telephone to the person or caregiver.
10. The method of claim 1, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of the given clinical study.
11. The method of claim 1, wherein in step (c) a determination is made not to provide the person or caregiver with notice of the given clinical study.
12. The method of claim 1, wherein in step (a) the registration information includes a user id, a password, electronic mail address or telephone number, zip code, first name or preferred name, gender, date of birth, whether the person is interested in clinical study information, new medical therapies, or participating in clinical studies.
13. The method of claim 1, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of an investigator associated with the study.
14. The method of claim 2, wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources.

15. The method of claim 1, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database.

16. A method for identifying subjects eligible to participate in a clinical study, comprising the steps of:

(a) accessing a computer database that stores information about a plurality of persons; wherein for each of said plurality listed in the database, the database includes a geographic location of the person, an age and a gender of the person, and disease conditions of interest to the person;

(b) submitting a query to the database, wherein the query includes criteria that reflect eligibility characteristics for persons suitable for participation as subjects in the clinical study; and

(c) identifying de-identified data records of persons likely to be subjects eligible for the clinical study based on the query.

17. The method of claim 16, further comprising the steps of:

(d) evaluating a feasibility of the clinical study based on the result of step (c);

(e) exploring the feasibility of the clinical study by modifying the criteria and repeating steps (b)-(d) using the modified criteria.

18. The method of claim 16 or 17, wherein step (b) includes querying a therapeutic incidence area database.

19. The method of claim 16 or 17, wherein step (b) includes querying an investigator database.
20. The method of claim 16 or 17, wherein the accessed information was submitted by e-mail, regular mail, and personally.
21. The method of claim 16 or 17, wherein the database includes a user id, a password, electronic mail address or telephone number, zip code, first name or preferred name, whether the person is interested in clinical study information, whether the user is interested in new medical therapies, and whether the person is interested in participating in clinical studies.
22. The method of claim 16 or 17, wherein the criteria that reflect eligibility characteristics include medications taken by the person, the person's geographic location, disease conditions experienced by the person, and a geographic location of an investigator associated with the clinical study.
23. The method of claim 16 or 17, wherein the database is accessed by a user through a web site, wherein there is a first firewall between the web site and the user and a second firewall between the web site and the database.
24. The method of claim 16 or 17, wherein the database includes genetic sequence information for each of said plurality listed in the database.

25. The method of claim 16 or 17, wherein the criteria that reflect eligibility characteristics include inclusion/exclusion criteria for the clinical study.

26. An integrated on-line interactive forum that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subjects, comprising:

(a) an investigator database that contains information suitable for identification of qualified investigators for clinical studies sponsored by the sponsors;

(b) a subject database that contains information suitable for identification of eligible subjects for clinical studies sponsored by the sponsors; and

(c) an extranet coupled to the investigator database and the subject database that allows sponsors and investigators to securely exchange documents required to launch a clinical study.

27. The forum of claim 26, further comprising one or more web pages that provide information describing clinical studies to potential clinical study subjects and permit potential clinical study subjects to register for inclusion in the subject database.

28. The forum of claim 26 or 27, wherein privacy is protected by denying sponsors access to identifying information stored in the subject database.

29. The forum of claim 28, wherein the identifying information is provided to the qualified investigators for potential subjects in a clinical study.

30. The forum of claim 26 or 27, wherein a web server is used for identifying potential subjects for clinical studies.
31. The forum of claim 26 or 27, wherein a web server is used for identifying qualified investigators for clinical studies.
32. The forum of claim 26 or 27 further including a therapeutic incidence area database.
33. The forum of claim of 27 wherein the extranet and the one or more web pages are accessed using different URLs.
34. The forum of claim 26 further comprising a website coupled to the extranet that includes content available online for training clinical study investigators.
35. The forum of claim 27 further comprising a website coupled to the extranet that includes content available from online for training clinical study investigators.
36. The forum of claim 26 further comprising a link from the subject database to an electronic data capture company.
37. The forum of claim 27 further comprising a link from the subject database to an electronic data capture company.

38. The forum of claim 26 or 27 further comprising a link to the subject database from an electronic medical records company.

39. The forum of claim 26 or 27 further comprising a study listing database.

40. A method for identifying a qualified investigator to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores a geographic location of each of a plurality of investigators; wherein the database also stores an incidence or a prevalence of each of a plurality of disease conditions in each of a plurality of different geographic locations;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the clinical study; and

wherein the qualified investigator is identified from the database based on the query and in accordance with the incidence or prevalence of the selected disease condition in the geographic location of the qualified investigator.

41. A method for identifying a qualified investigator to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores a geographic location of each of a plurality of investigators; wherein the database also stores a geographic location of subjects for the study;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the clinical study; and

wherein the qualified investigator is identified from the database based on the query and in accordance with the geographic location of subjects for the study.

42. The method of claim 41 wherein the database also stores an incidence or a prevalence of each of a plurality of disease conditions in each of a plurality of different geographic locations; and wherein the qualified investigator is identified from the database also based on the incidence or prevalence of the selected disease condition in the geographic location of the qualified investigator.

43. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to the prescription writing history of the investigator with respect to a plurality of medications; and

wherein the database also stores information that associates each of the medications with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a given investigator is identified from the database based on the query and in accordance with the given investigator's prescription writing history.

44. The method of claim 43 wherein the prescription writing history of the investigator is provided by the investigator to the database.

45. The method of claim 43 wherein the prescription writing history of the investigator is provided by a party other than the investigator to the data.

46. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to a history of laboratory procedure requests made by the investigator; and

wherein the database also stores information that associates each of the historical laboratory procedure requests with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a given investigator is identified from the database based on the query and in accordance with the given investigator's historical laboratory request information.

47. The method of claim 46 wherein the investigator's historical laboratory procedure results are provided by the investigator to the database.

48. The method of claim 46 wherein the investigator's historical laboratory procedure results are provided by a party other the investigator to the database.



49. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

- (a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to past participation of the investigator in clinical studies;
- (b) submitting a query to the database, wherein the query includes criteria corresponding to past clinical study experience suitable to qualify investigators for participating in a clinical study; and
- (c) identifying qualified investigators from the database based on the query.

50. The method of claim 49 wherein the past participation of the investigator is provided by the investigator to the database.

51. The method of claim 49 wherein the past participation of the investigator is provided by a party other than the investigator to the database.

52. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

- (a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to a medical specialty of the investigator; and
- wherein the database also stores information that associates the medical specialty with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the given investigator's medical specialty.

53. The method of claim 52 wherein the investigator's medical specialty information is provided by the investigator to the database.

54. The method of claim 52 wherein the investigator's medical specialty is provided by a party other than the investigator to the database.

55. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to experience of a medical staff of the investigator; and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a qualified investigator is identified from the database based on the query and in accordance with the experience of the medical staff of the qualified investigator's medical specialty.

56. The method of claim 55 wherein the information regarding experience of the investigator's medical staff information is provided by the investigator to the database.

57. The method of claim 55 wherein the information regarding experience of the investigator's medical staff information is provided by a party other the investigator to the database.

58. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to how many clinical studies have been performed by the investigator;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with how many clinical studies have been performed by the qualified investigator.

59. The method of claim 58 wherein the information corresponding to how many clinical studies have been performed by the investigator is provided by the investigator to the database.

60. The method of claim 59 wherein the information corresponding to how many clinical studies have been performed by the investigator is provided by a party other the investigator to the database.

61. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to hospital affiliations of the investigator; and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's hospital affiliations.

62. The method of claim 61 wherein the investigator's hospital affiliations information is provided by the investigator to the database.

63. The method of claim 61 wherein the investigator's hospital affiliations is provided by a party other the investigator to the database.

64. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to a number of beds in hospital affiliations of the investigator; and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the number of beds in hospital affiliation of the qualified investigator.

65. The method of claim 64 wherein the number of beds in hospital affiliations of the investigator is provided by the investigator to the database.

66. The method of claim 64 wherein the number of beds in hospital affiliations of the investigator is provided by a party other the investigator to the database.

67. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to insurance provider affiliations of the investigator; and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the insurance provider affiliations of the qualified investigator.

68. The method of claim 67 wherein the insurance provider affiliations of the investigator is provided by the investigator to the database.

69. The method of claim 67 wherein the insurance provider affiliations of the investigator is provided by a party other the investigator to the database.

70. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to mandated IRB relationships of the investigator; and

wherein the database also stores information that associates the mandated IRB relationships with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the mandated IRB relationships of qualified investigator.

71. The method of claim 70 wherein the mandated IRB relationships of the investigator is provided by the investigator to the database.

72. The method of claim 70 wherein the mandated IRB relationship of the investigator is provided by a party other the investigator to the database.

73. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

- (a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to regulatory agency audits of the investigator; and
- (b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a qualified investigator is identified from the database based on the query and in accordance with the regulatory agency audits information of the qualified investigator.

74. The method of claim 73 wherein the information corresponding to regulatory agency audits of the investigator is provided by the investigator to the database.

75. The method of claim 73 wherein the information corresponding to regulatory agency audits of the investigator is provided by a party other the investigator to the database.

76. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

- (a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to PRF affiliations of the investigator; and

wherein the database also stores information that associates the PRF affiliations with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's PRF affiliations.

77. The method of claim 76 wherein the investigator's PRF affiliations information is provided by the investigator to the database.

78. The method of claim 76 wherein the investigator's PRF affiliation information is provided by a party other the investigator to the database.

79. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to equipment of the investigator; and

wherein the database also stores information that associates the equipment of the investigator with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and



wherein a qualified investigator is identified from the database based on the query and in accordance with the equipment of the qualified investigator.

80. The method of claim 79 wherein the investigator's equipment information is provided by the investigator to the database.

81. The method of claim 79 wherein the investigator's equipment information is provided by a party other the investigator to the database.

82. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to the investigator's practice setting; and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's practice setting.

83. The method of claim 82 wherein the investigator's practice setting information is provided by the investigator to the database.

84. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to the investigator's city and state of practice; and wherein the database also stores information that associates the investigator's city and state of practice information with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's city and state of practice information.

85. The method of claim 84 wherein the investigator's city and state of practice information is provided by the investigator to the database.

86. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to the investigator's name;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's name.

87. The method of claim 86 wherein the investigator's medical specialty information is provided by the investigator to the database.

88. The method of claims 43, 44, or 45 wherein the query further includes search criteria selected from the group consisting of, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to the medical specialty of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each

of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

89. The method of claims 46, 47, or 48 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to past participation of the investigator in clinical studies, information corresponding to the medical specialty of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

90. The method of claims 49, 50, or 51 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to the medical specialty of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

91. The method of claims 52, 53, or 54 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the

investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

92. The method of claims 55, 56, or 57 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information

corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

93. The method of claims 58, 59, or 60 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice,

investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

94. The method of claims 61, 62, or 63 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of



disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

95. The method of claims 64, 65, or 66 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

96. The method of claims 67, 68, or 69 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

97. The method of claims 70, 71, or 72 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the

investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

98. The method of claims 73, 74, or 75 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information

corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

99. The method of claims 76, 77, or 78 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the

investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

100. The method of claims 79, 80, or 81 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of

disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

101. The method of claims 82 or 83 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

102. The method of claims 84 or 85 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

103. The method of claims 86 or 87 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical

studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's city and state of practice.

104. A method for developing a permission based online database, comprising the steps of:

(a) presenting one or more web pages that allow a person to register with a database by submitting registration information to the database, wherein the registration information includes name information and contact information and permission information indicating whether the person wishes to receive notice of one or more clinical studies;

(b) automatically registering the person with the database upon receipt of the registration and permission information;



(c) obtaining permission from the person to send information regarding drugs, medical devices or medical therapies;

(d) building the database by repeating steps (a) through (c); and

(e) generating a list for use in marketing drugs, medical devices and medical therapies to persons by querying the database using criteria associated with the drugs, medical devices or medical therapies.

105. The method of claim 104, further comprising the steps of:

(f) automatically determining, in accordance with the registration and permission information, whether to provide the person with notice of a clinical study associated with a disease condition of interest to the person;

(g) automatically presenting a questionnaire associated with the given clinical study to the person; and

(h) storing answers submitted by the person in the database.

106. The method of claim 104, further comprising the step of sending information to persons on the list regarding a drug, medical device and medical therapy.

107. A method of maintaining the confidentiality of clinical study information associated with each of a plurality of clinical study sponsors, comprising the steps of:

(a) receiving said clinical study information from said plurality of clinical study sponsors; and

(b) storing said clinical study information in a database;

wherein each sponsor is permitted full access to said clinical study information submitted by that sponsor and only aggregated access to information submitted by other sponsors.

108. The method of claim 107 wherein said clinical study information comprises at least one of investigator information, sponsor identification, protocol information, drug indication information, drug class information, clinical study enrollment goal information, actual clinical study enrollment information, and clinically evaluable subjects information.

109. The method of claim 108 wherein each sponsor is denied access to said protocol information, said drug class information and said sponsor identification information of other sponsors.

110. A method for ranking a clinical investigator, comprising the steps of:

(a) selecting at least two ranking criteria from the group consisting of investigator experience, professional certification, scientific leadership, regulatory audits and study coordinator experience; and

(b) determining the ranking for the clinical investigator by generating a composite ranking score from the at least two ranking criteria.

111. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to a history of laboratory results of the investigator; and

wherein the database also stores information that associates each of the laboratory results with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a given investigator is identified from the database based on the query and in accordance with the given investigator's historical laboratory results information.

112. The method of claim 111 wherein the history of laboratory results of the investigator is provided by the investigator to the database.

113. The method of claim 111 wherein the history of laboratory results of the investigator is provided by a party other than the investigator to the database.

114. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

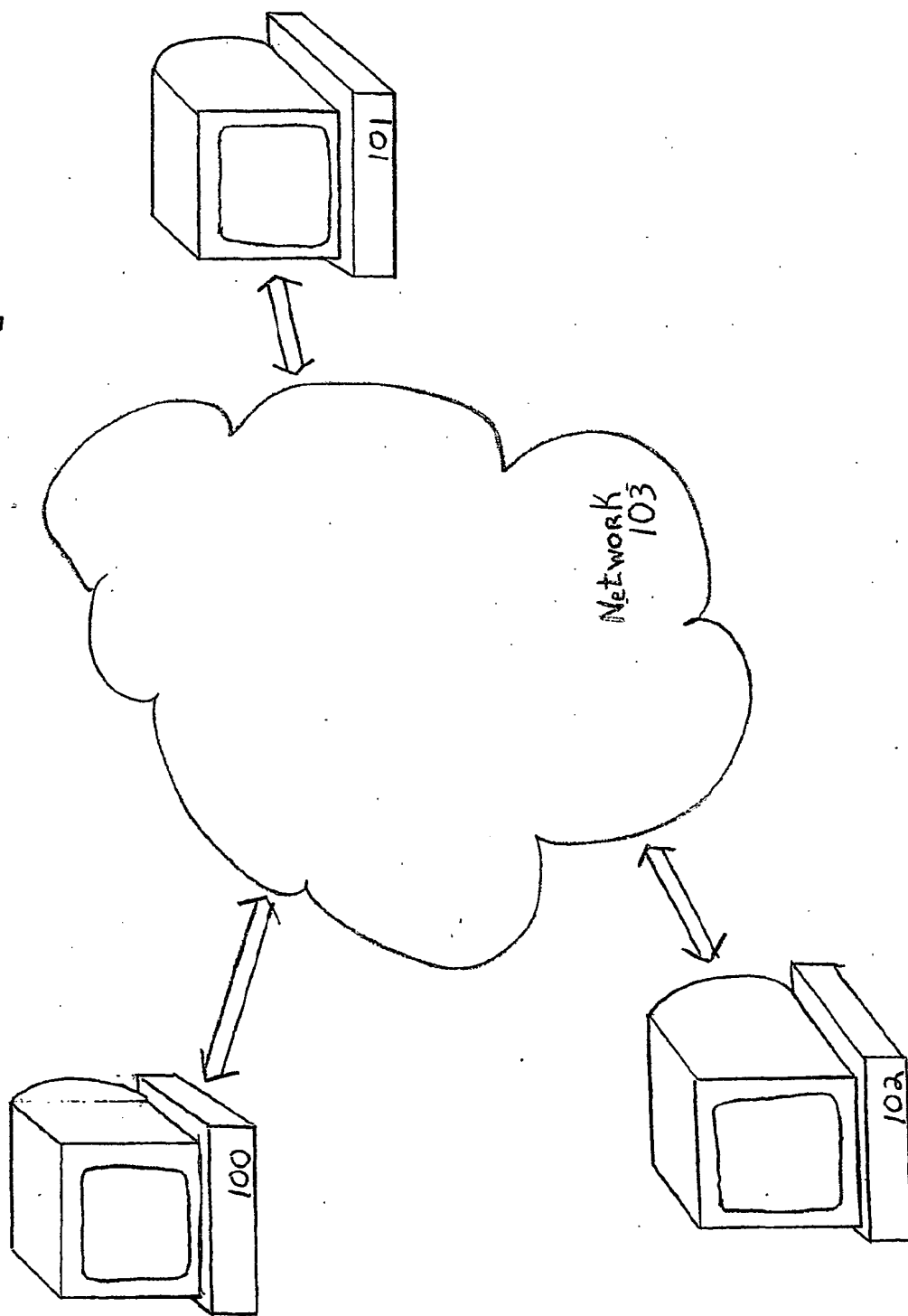
(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to services performed in hospital affiliations of the investigator; and wherein the database also stores information that associates the services performed in hospital affiliations with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a qualified investigator is identified from the database based on the query and in accordance with the services performed in hospital affiliations of the qualified investigator.

115. The method of claim 114 wherein the services performed in hospital affiliations of the investigator is provided by the investigator to the database.
116. The method of claim 114 wherein the services performed in hospital affiliations of the investigator is provided by a party other than the investigator to the database.
117. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:
- (a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to claims information of the investigator; and wherein the database also stores information that associates the claims information with one or more disease conditions;
  - (b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a qualified investigator is identified from the database based on the query and in accordance with the claims information.
118. The method of claim 117 wherein the claims information of the investigator is provided by the investigator to the database.
119. The method of claim 117 wherein the claims information of the investigator is provided by a party other than the investigator to the database.

120. The method of claim 107 wherein the aggregated access provides a lesser degree of detail of said information.

Fig. 1A



100

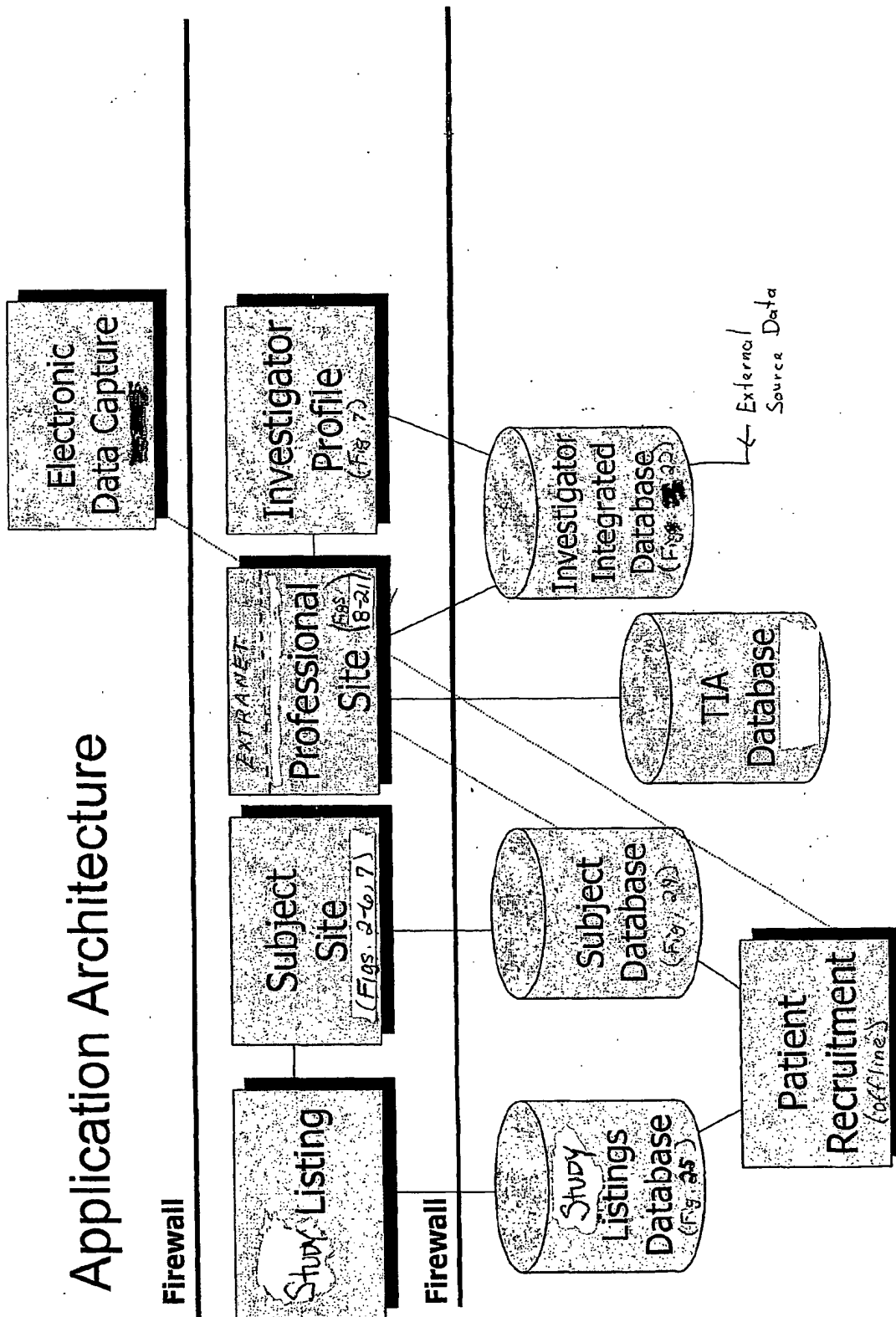


Fig. 1B

Search

Search clinical trials

Go

## Register

To register to become a member, just fill in the form below.

201 Email

202 Username

203 Password

203 Retype Password

Username 4-digits chars, no blank spaces

Password 4-digits chars, case-sensitive

Your privacy is of the utmost concern to us. For more information, read [Privacy & Security Policy](#).

As part of the registration process and to protect your privacy, we ask that you please choose one of the questions in the box below and type the answer into the second box. If you forget your password, this question will be given to you. After correctly answering the question, you will be asked to reset your password so you can have full access to the site.

205 Your question

What is your mother's maiden name?

205 Your answer, up to 45 characters.

### Terms of Service

Please read the following Terms of Service agreement.

TERMS OF SERVICE AGREEMENT

☒ I Agree

☐ I Do Not Agree

### Benefits of Registration

Registered users will benefit from:

Fig. 2A



- OUR comprehensive clinical trial listings - get trial information and out how you can be considered for participation in clinical trials
- The ability to ask questions of OUR medical experts
- Timely, relevant announcements of new trials and drug information
- Exclusive interactive tools, including your own personal library of news information
- Emails informing you of updates to our clinical trial listings, news and information, tailored to your selection.
- A personal profile used to optimize your experience.

FIG. 2B

Search

Search clinical trials

Home /

### Personal Information

Add or modify your name, password, address and other information about you.

**Personal Information**  
Medical Condition  
Contacts

**Feature Stories**  
**News Archive**  
**Ask the Expert**  
**About Clinical Trials**  
**Tutorial**

**Therapeutic Area**  
**Cancer**  
**Neurological Conditions**

**Register Now**  
Review Clinical Trials  
Ask Questions and More

First Name   
Last Name   
Phone #     
ext.   
Address   
City   
State   
ZIP Code   
Email   
Gender ☒ Male ☐ Female

300

301

302

Show My Library welcome page ☒ Yes ☐ No  
Show My Profile welcome page ☒ Yes ☐ No

Fig. 3

Search  Search clinical trials

Home /

## Medical Conditions

Select conditions that interest you and indicate the kind of information you would like to receive. Please select a therapeutic area in the pulldown menu and then click "View" to see the conditions that fall within that area.

If you'd like to see another therapeutic area, simply go to the pulldown menu, make another selection and then click "View." The page will automatically display the new therapeutic area.

**Therapeutic Area**

- Feature Stories
- News Archive
- Ask the Expert
- About Clinical Trials
- Tutorial
- Cancer
- Neurological Conditions

**Personal Information**

**Medical Condition**

**Contact**

**Register Now**  
Review Clinical Trials,  
Ask Questions and More

**Cancer**  **View**

Please email me updated information on:

Condition	Medical News/Drugs	Clinical Trial Opportunities
Abdominal Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Acute T-Cell Lymphoma	<input type="checkbox"/>	<input type="checkbox"/>
Adrenal Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Bladder Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Bone Marrow Transplant	<input type="checkbox"/>	<input type="checkbox"/>
Bone Metastases	<input type="checkbox"/>	<input type="checkbox"/>
Brain Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Breast Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Cancer Pain	<input type="checkbox"/>	<input type="checkbox"/>
Cancer/Tumors	<input type="checkbox"/>	<input type="checkbox"/>
Cervical Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Cervical Neoplasia	<input type="checkbox"/>	<input type="checkbox"/>
Chemotherapy	<input type="checkbox"/>	<input type="checkbox"/>
Colon Malignancies	<input type="checkbox"/>	<input type="checkbox"/>
Colon Polyps	<input type="checkbox"/>	<input type="checkbox"/>
Colorectal Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Effects of Chemotherapy	<input type="checkbox"/>	<input type="checkbox"/>
Endometrial Cancer	<input type="checkbox"/>	<input type="checkbox"/>

FIG. 4A

Esophageal Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Fibrocystic Breast	<input type="checkbox"/>	<input type="checkbox"/>
Gall Bladder Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Gastric Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Gliomas	<input type="checkbox"/>	<input type="checkbox"/>
Head and Neck Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Hepatoblastoma	<input type="checkbox"/>	<input type="checkbox"/>
Histiocytoma	<input type="checkbox"/>	<input type="checkbox"/>
Islet Cell Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Kaposi's Sarcoma	<input type="checkbox"/>	<input type="checkbox"/>
Kidney Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Leukemia	<input type="checkbox"/>	<input type="checkbox"/>
Liver Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Lung Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Lymphomas	<input type="checkbox"/>	<input type="checkbox"/>
Malignant Adenoma	<input type="checkbox"/>	<input type="checkbox"/>
Malignant Melanoma	<input type="checkbox"/>	<input type="checkbox"/>
Medical Prosthetics	<input type="checkbox"/>	<input type="checkbox"/>
Meningiomas	<input type="checkbox"/>	<input type="checkbox"/>
Mesothelioma	<input type="checkbox"/>	<input type="checkbox"/>
Metastatic Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Multiple Myelomas	<input type="checkbox"/>	<input type="checkbox"/>
Mycosis	<input type="checkbox"/>	<input type="checkbox"/>
Fungoides	<input type="checkbox"/>	<input type="checkbox"/>
Neoplasms	<input type="checkbox"/>	<input type="checkbox"/>
Neurectoderma	<input type="checkbox"/>	<input type="checkbox"/>
Neuroblastoma	<input type="checkbox"/>	<input type="checkbox"/>
Neurofibromatosis	<input type="checkbox"/>	<input type="checkbox"/>
Non-Hodgkin's Lymphoma	<input type="checkbox"/>	<input type="checkbox"/>
Oral Cavity Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Ovarian Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Pancreatic Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Pelvic Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Platelet Deficiencies	<input type="checkbox"/>	<input type="checkbox"/>
Prostate Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Rectal Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Renal Cell Carcinoma	<input type="checkbox"/>	<input type="checkbox"/>
Sarcoma	<input type="checkbox"/>	<input type="checkbox"/>
Skin Cancer	<input type="checkbox"/>	<input type="checkbox"/>

Fig. 4B

Spinal Cord	<input type="checkbox"/>	<input type="checkbox"/>
Malignancy	<input type="checkbox"/>	<input type="checkbox"/>
Stomach Cancer	<input type="checkbox"/>	<input type="checkbox"/>
T-Cell Lymphoma	<input type="checkbox"/>	<input type="checkbox"/>
Testicular Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Thrombocytopenia	<input type="checkbox"/>	<input type="checkbox"/>
Thymomas	<input type="checkbox"/>	<input type="checkbox"/>
Vaginal Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Vulvar Carcinoma	<input type="checkbox"/>	<input type="checkbox"/>
Wilms' Tumor	<input type="checkbox"/>	<input type="checkbox"/>

---


 Save

FIG. 4C

Clinical

Search clinical trials

[Home / About Us /](#)

## About Clinical Trials

### Search Clinical Trials

- Feature Stories
- News Archive
- Ask the Expert
- About Clinical Trials
- Tutorial

#### Therapeutic Area

- Cancer
- Neurological Conditions

**502**

- Cancer
- Cardiology/Vascular Diseases
- Dental/Maxillofacial Surgery
- Dermatology Plastic Surgery
- Endocrinology
- Gastroenterology
- Hematology
- Immunology/Infectious Diseases
- Musculoskeletal
- Nephrology/Urology
- Neurological Conditions
- Obstetrics/Gynecology
- Ophthalmology
- Otolaryngology
- Pediatrics/Neonatology
- Pharmacology/Toxicology
- Pulmonary/Respiratory Diseases
- Rheumatology
- Trauma/Emergency Medicine

**501**

**Register Now.**  
Review Clinical Trials  
Ask Questions and More

### Clinical Trials FAQ

- [Introduction: What are clinical trials?](#)
- [Why are clinical trials important?](#)
- [The clinical trial process.](#)
- [How are participant's rights and safety protected during a clinical trial?](#)
- [Who pays for clinical trials?](#)
- [Where can you get more information about clinical trials?](#)
- [Questions you need to ask.](#)
- [Common terms used in clinical trials.](#)

**503**

### Introduction: What are clinical trials?

Quite simply, a clinical trial is a very carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.

When a promising new medication is identified, the drug undergoes careful evaluation for safety and effectiveness through the clinical trial process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. The pharmaceutical or biotechnology company that is sponsoring the trial reports their findings to the U.S. Food and Drug Administration (FDA). The FDA reviews those findings and if they determine that the drug is both effective and safe to use, then they will make the

Fig. 5A

drug available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for clinical trials that may be beneficial for you, please search our clinical trials listing for details on type and location. This is the first step to review the exciting medical research on the potential new treatments of tomorrow that may benefit you today.

[Back to top](#)

### **Why are clinical trials important?**

Clinical trials are important to increase medical knowledge and find better ways to help people. Generally, the goal of clinical trials is to introduce an investigational treatment that is safer and more effective than the standard treatment for a particular disease or condition. In addition, for those diseases for which there are no treatment options, research and clinical trials may be the only avenue to uncover a potential treatment.

[Back to top](#)

### **The clinical trial process.**

After a drug is successfully tested in laboratory and animal studies, the FDA grants approval for testing to begin in humans. The testing of drugs in clinical trials - also called clinical studies or clinical research - usually occurs in three and sometimes four different phases or steps. Each phase normally involves a larger number of people.

**Phase I.** In Phase I trials, researchers study how quickly an investigational treatment works and how the human body processes the investigational treatment. They also try to find dose ranges that will produce the desired effects. Phase I trials typically involve healthy volunteers, but sometimes severely ill patients will participate in these trials.

**Phase II.** In these trials, the safety and effectiveness of an investigational treatment is studied in larger groups of people who have the disease or condition to be treated.

FIG. 5B

11/89

**Phase III.** In Phase III trials, the safety and effectiveness of an investigational treatment are studied in larger populations of people for whom the drug is intended. Typically, there are hundreds or thousands of people in a Phase III trial. Often, the investigational treatment is compared with standard treatments in hopes of finding better ways to help people. The pharmaceutical or biotechnology company that is sponsoring the trial reports the findings from Phase III trials to the U.S. Food and Drug Administration (FDA).

**Phase IV.** Phase IV trials are also called post-marketing trials. Only after the FDA has determined that the medicine is both safe to use and equivalent or superior to existing therapies is it then made available for broader use by physicians and their patients. Phase IV trials take place after a drug has been approved. Findings from Phase IV trials provide additional information about the safety and efficacy of the drug.

⦿ Back to top

#### **How are participant's rights and safety protected during a clinical trial?**

The FDA is the government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The rights and safety of people participating in clinical trials are also protected by an Institutional Review Board and by an informed consent form. An Institutional Review Board (IRB) is comprised of both physicians and lay people for the purpose of studying the design of the trial and ensuring that participant's rights are maintained. The informed consent form explains the clinical trial and outlines a participant's rights. You should always be given an informed consent form prior to enrolling in any clinical trial.

⦿ Back to top

#### **Who pays for clinical trials?**

- Sponsors fund clinical trials. This funding can come from the federal government via the National Institutes of Health (NIH) or directly from pharmaceutical and biotech companies.
- The clinical trial sponsor contracts with specialized physicians and/or researchers to administrate the trial. Settings for the trials could range from the physician's office to a hospital or research facility. Reimbursement for this service is typically paid out on a per-patient basis.
- Sponsors may pay you to participate in a clinical trial. Typically, these fees, when provided, are nominal.
- Medical care is often provided at no cost to the

FIG 5C



12/89

patients, but they still may be responsible for other expenses such as travel between their homes and the healthcare facility.

Patients may also have to pay for some medical procedures, tests, or hospital stays if these are considered a part of standard treatment and not part of the clinical trial. Before you enroll, you should determine exactly who pays for what services.

[Back to top](#)

### **Where can you get more information about clinical trials?**

If you or someone you know has a medical problem and is thinking about taking part in a clinical trial, speak to your healthcare provider first. In taking an active role in the management of your health, you may want to work closely with your provider to find out if a particular clinical trial is right for you.

[Back to top](#)

### **Questions you need to ask.**

- What is the length of your involvement in the clinical trial? How long will the trial last?
- Where will you have to go in order to participate in the clinical trial?
- What are the possible treatments you may receive while in the clinical trial?
- Do the treatment alternatives they provide cover all possible treatments for this disease? If not, what are your other treatment alternatives?
- What procedures are built into the study to keep you safe from harm while you are participating?
- What are the risks and benefits of participating in the clinical trial?
- If there are risks, what will happen should you have an adverse reaction to the treatment in the study?
- What costs may you incur if you participate?
- Will the treatment be available to you even after the clinical trial has concluded?
- Where are the funds coming from to conduct this trial? What is their purpose in sponsoring the trial?

You should also feel free to ask any other question about the trial you want answered.

[Back to top](#)

### **Common terms used in clinical trials.**

**Clinical trial:** A clinical trial - also called a clinical study or clinical research - is a way to evaluate the safety and

Fig 5D

benefits of a new drug in a carefully controlled setting. The new drug is tested in people who volunteer to participate in the trial.

**Clinical investigator:** A clinical investigator is a doctor or scientist who is responsible for carrying out the planned research activities for a clinical trial. Typically, the doctors chosen for these clinical activities are experts within their medical specialties.

**Coordinator:** A coordinator is a person (usually a nurse or other medical professional) who is responsible for organizing the planned clinical research activities for a trial. The coordinator is also responsible for taking care of important study documents.

**Food and Drug Administration:** The Food and Drug Administration is often referred to as the FDA. The FDA is a government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The FDA also enforces the laws that govern the approval, regulation and monitoring of drugs and medical devices.

**Informed consent:** Informed consent is a process that confirms a patient understands the nature of the study, the risks involved, and the expected benefits of treatment. A written and dated form called the "informed consent form" is signed by a patient to document this process.

**Institutional Review Board:** An Institutional Review Board is usually referred to as the "IRB." The IRB is a group of medical, scientific, and nonscientific people that are responsible for reviewing and approving the planned clinical activities of a study. The group ensures the protection of the rights, safety, and well-being of patients who volunteer for clinical trials.

**Investigational treatment:** Investigational treatment is another term for the drug, treatment, or medical device that is studied in a clinical trial.

**Principal investigator:** The principal investigator is the doctor or researcher who is put in charge of all clinical activities at a particular study location and who supervises the care of patients in the study.

**Protocol:** A protocol is a plan that contains guidelines for a clinical study. The pharmaceutical or biotechnology company that discovered the investigational treatment usually develops the protocol.

**Sponsor:** The sponsor is the organization that funds a clinical trial and that develops a plan for the research. The organizations can be a pharmaceutical or biotech company, a research institution, or other health organization.

FIG. 5E

**Standard treatment:** Standard treatment is a term that refers to approved medical procedures, drugs, tests, or hospitalizations that are a part of the general care considered to be appropriate for certain diseases and conditions. It is the 'best treatment' currently known for a given disease. If there are no current treatments shown to be effective against a particular disease, then no treatment would be the standard treatment for that condition.

[⌂ Back to top](#)

FIG. 5F

## Clinical

Search

Search clinical trials

Home / Cancer /

Clinical Trials

Search Clinical Trials

Use these search criteria to find clinical trials.

Select a condition

and/or

Select a state

600

601

602

603

Contact me for a clinical trial

604

Welcome to Clinical Trials

When a promising new medication is identified, careful evaluation of the safety and effectiveness of the drug then occurs in the clinical trials process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. Findings from the clinical trials are reported by the pharmaceutical or biotechnology company that is sponsoring the clinical trial to the US Food and Drug Administration — the FDA. Only after the FDA has determined from reviewing the findings from clinical trials that the medicine is both safe to use and effective is it then made available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for information on where clinical trials are taking place and the types of trials that are available, you can search our clinical trials listing. If you want to learn more about clinical trials, please see our About Clinical Trials page. These are the first steps in learning about clinical trials and in deciding how medical research on

Feature Stories

News Archive

Ask the Expert

About Clinical Trials

Tutorial

Therapeutic Area

Cancer

Neurological Conditions

Register Now

Review Clinical Trials

Ask Questions and More

1 of 2

Fig. 6A

BNSDOCID: <WO 0155942A1\_1>

clinical trials and in deciding how medical research on possible treatments for tomorrow may help you today.

About Clinical Trials will provide you with more information.

FIG. 6B

Search  Search clinical trials

**General Trial Interest Form** 605

Please select the therapeutic areas and the specific conditions that interest you. Select up to three conditions below. Your selection(s) will be saved to the Medical Conditions section of My Profile, where you can select additional conditions.

Primarily interested 606

☒ for myself  
☐ for someone else

Select therapeutic area  607

Select therapeutic area

Select therapeutic area

How would you like us to contact you?

☒ by email 608  
☐ by phone  
☐ by regular mail

First Name

Last Name

Phone #

ext.

Email

Address

City

State

ZIP Code

Best time to contact you

Willing to travel

FIG. 6C 609

610 611

home | register | login | my library | my profile | about us | help

Search:

Search clinical trials

## Register Step 1 of 3

**Welcome!**

To register with  we invite you to complete the following questionnaire about you and your health. This should take approximately 5 minutes to complete.  will use the information to present you with new medical therapy and clinical trial information that is of specific interest to you.

Your privacy and security are very important to us; therefore we encourage you to review our [Privacy & Security Policy](#).

### Choose Your Username and Password

Please choose a username

Please choose a password

Please re-type your password

Choose your reminder question

Please enter your answer to the question

**Are you seeking information for yourself, or for someone else?**

☒ I am seeking information for myself

☐ I am seeking information for someone else

with

Feature Articles  
Medical News  
Ask the Expert  
All About Clinical Trials  
Tutorial

Therapeutic Area

Cancer  
Neurological Conditions

Register Now  
Review Clinical Trials  
Ask Questions and More

Internet

Fig. 6D

home | register | login my library | my profile | about us | help

Search: Search clinical trials

**Personal Information / Medical Conditions** Step 2 of 3

*\* denotes required information*

**Personal Information**

Salutation

First Name \*   
(Please enter your first name or the name you prefer to be called when you are welcomed to the site.)

Last Name

Birthdate (month/year)\*

Gender \*

Ethnic Background

**Contact Information**

Email Address \*

Telephone Number  -  -  ext.

Postal or Zip Code \*

Country

☐ I do not want to receive information by e-mail.

**Medical Conditions**

By completing this section, you will help us to provide you with information that meets your interests.

I am interested in the following conditions \* (you may choose more than one):

Medical Conditions: \*

Acne  
AIDS/HIV  
Allergies  
Alopecia (Hair Loss)

My Conditions:

Alopecia (Hair Loss)  
Cancer: Prostate  
Seizures (Epilepsy)

Fig. 6E



home | register | login my library | my profile | about us | help

Search:  Search clinical trials

**Information Request** Step 3 of 3

I would like to receive information about my conditions:

**Alopecia (Hair Loss):**

☐ Send me Clinical Trial Opportunities  
☐ Send me News and New Medical Therapies  
☐ Do not send me information

**Cancer - Prostate:**

☐ Send me Clinical Trial Opportunities  
☐ Send me News and New Medical Therapies  
☐ Do not send me information

**Seizures (Epilepsy):**

☐ Send me Clinical Trial Opportunities  
☐ Send me News and New Medical Therapies  
☐ Do not send me information

**Terms and Conditions**

Please read the following Terms and Conditions Agreement.

**TERMS AND CONDITIONS**

By selecting "I Accept", you are accepting the Terms and Conditions above and will become a registered user.

Fig. 6F

home | register | login my library | my profile | about us | help

Search  Search clinical trials

**Therapeutic Area**  
  
  
  
  
Review Clinical Trials  
Ask Questions and More

## Registration Complete

Thank you for registering with .US.

Your request to receive information about the conditions you selected is being processed; you should receive updates periodically.

As a result of your interest in clinical trial opportunities, we would like to ask you additional questions about your health and medical condition(s). These questions are similar to what a doctor, or other medical professional would ask you when you are being screened for participation in a specific clinical trial. This information is important in determining your possible preliminary eligibility for a specific clinical trial.

Please take a few more minutes to answer the next set of questions, and keep in mind that these are optional. If you do not have time to complete the additional questions right now, you may update your profile the next time you login to acurian.com. Would you like to continue?

Done Internet

Fig. 6G

home | register | login | my library | my profile | about us | help

Search clinical trials

**Medications (Optional)** Step 1 of 5

Are you taking prescription (Rx) or over-the-counter (OTC) medications for these conditions?

Your Medical Conditions	Prescription	Over-the-Counter	No Medications
Alopecia (Hair Loss)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cancer : Prostate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Seizures (Epilepsy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Do you take medications for any of the following conditions:

Medication	Yes	No
Allergies or Asthma	<input type="radio"/>	<input type="radio"/>
Heartburn	<input type="radio"/>	<input type="radio"/>
Diabetes	<input type="radio"/>	<input type="radio"/>
High Blood Pressure	<input type="radio"/>	<input type="radio"/>
Pain	<input type="radio"/>	<input type="radio"/>
Thyroid Disorders	<input type="radio"/>	<input type="radio"/>
Heart Conditions	<input type="radio"/>	<input type="radio"/>

Done

Fig. 6H

home | register | login my library | my profile | about us | help

Search  Search clinical trials

**Health Habits (Optional)** Step 2 of 5

It is often important to know your health habits when presenting you with possible clinical trial opportunities

How often do you exercise?

☐ Never  
☐ Once a week  
☐ Twice a week  
☐ Three times a week  
☐ Four or more times a week  
☐ Daily

How often do you visit your primary care physician?

☐ Once a year  
☐ 2-4 times a year  
☐ Every month  
☐ I do not have a primary care physician

Do you smoke cigarettes?

☐ No, I have never smoked  
☐ No, I quit smoking  
☐ Yes, daily  
☐ Yes, occasionally

If you smoke, how many cigarettes do you smoke per day?

Please enter:  Cigarettes Per Day

If you smoke, how old were you when you started smoking?

Please enter:  years old

Do you drink alcoholic beverages?

☐ No  
☐ Yes, occasionally  
☐ Yes, 1-2 drinks per day  
☐ Yes, more than 2 drinks per day

Overall, how would you rate your health?

☐ Excellent  
☐ Good  
☐ Fair  
☐ Poor

**Left Sidebar:**

- ☐ Feature Articles
- ☐ Medical News
- ☐ Ask the Expert
- ☐ All About Clinical Trials
- ☐ Tutorial

**Therapeutic Area**

- ☐ Cancer
- ☐ Neurological Conditions

**Register Now**  
Review Clinical Trials  
Ask Questions and More

Fig. 6I

[home](#) | [register](#) | [login](#) | [my library](#) | [my profile](#) | [about us](#) | [help](#)

[Feature Articles](#)

[Medical News](#)

[Ask the Expert](#)

[All About Clinical Trials](#)

[Tutorial](#)

[Therapeutic Area](#)

[Cancer](#)

[Neurological Conditions](#)

[Register Now](#)  
Review Clinical Trials  
Ask Questions and More

### Clinical Trial Experience (Optional)

Step 3 of 5

A clinical trial is a carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.

The following questions ask about your experience and interest in participating in clinical trials. These questions are to help us know how many members of ourCS have participated in clinical trials before.

How many clinical trials have you participated in?

☐ 0

☐ 1

☐ 2 - 3

☐ 4 or more

How interested would you be in participating in a clinical trial for a drug that might be used to treat any medical condition(s) you may have?

☐ Very Interested

☐ Somewhat Interested

☐ Not Sure

☐ Not Interested

If interested in clinical trial participation, how far would you be willing to travel to participate in a clinical trial?

☐ 1 - 10 miles

☐ 11 - 50 miles

☐ 51 - 100 miles

☐ More than 100 miles

☐ Any distance

Done

Internet

Fig. 6J

home | register | login my library | my profile | about us | help

Search: Search clinical trials go

### Clinical Trial Questions Step 4 of 5

Earlier in the registration process, you expressed interest in clinical trial opportunities. When you are screened for a clinical trial, the doctor at the trial site needs to know more information about your health and the medical condition(s) for which you have been diagnosed. Your answers to the following questions may help determine if you may potentially qualify for a specific clinical trial.

Listed below are the conditions you selected earlier in the questionnaire. After you answer questions about each condition, a check mark will appear to the right. Your information will be saved after you complete each section. If you are unable to complete these at this time, we will ask you to update your profile the next time you login to acurian.com.

Condition	Questionnaire Complete
Alopecia (Hair Loss)	<input checked="" type="checkbox"/>
Cancer: Prostate	<input type="checkbox"/>
Seizures (Epilepsy)	<input type="checkbox"/>

[Save and Continue](#)

[Save and Return to Previous Activity](#)

[Register Now](#)  
[Review Clinical Trials](#)  
[Ask Questions and More](#)

[Feature Articles](#)  
[Medical News](#)  
[Ask the Expert](#)  
[All About Clinical Trials](#)  
[Tutorial](#)

**Therapeutic Area**  
[Cancer](#)  
[Neurological Conditions](#)

Internet

Fig. GK

home | register | login my library | my profile | about us | help

Search

**Feedback** Step 5 of 5

Thank you for taking the time to complete your profile.

The information you entered will be saved in the My Profile of our site. You may update this information at any time by selecting the My Profile button at the top of the page. We ask that you review your profile at least once a month, so that we may have the most accurate information when trying to present you with clinical trial or medical information.

Acurian welcomes your feedback. Please provide us with any comments you would like to share about the questions asked in this registration process.

Review Clinical Trials Ask Questions and More

Feature Articles  
Medical News  
Ask the Expert  
All About Clinical Trials  
Tutorial

Therapeutic Area  
Cancer  
Neurological Conditions

Done Internet

Fig. 6L

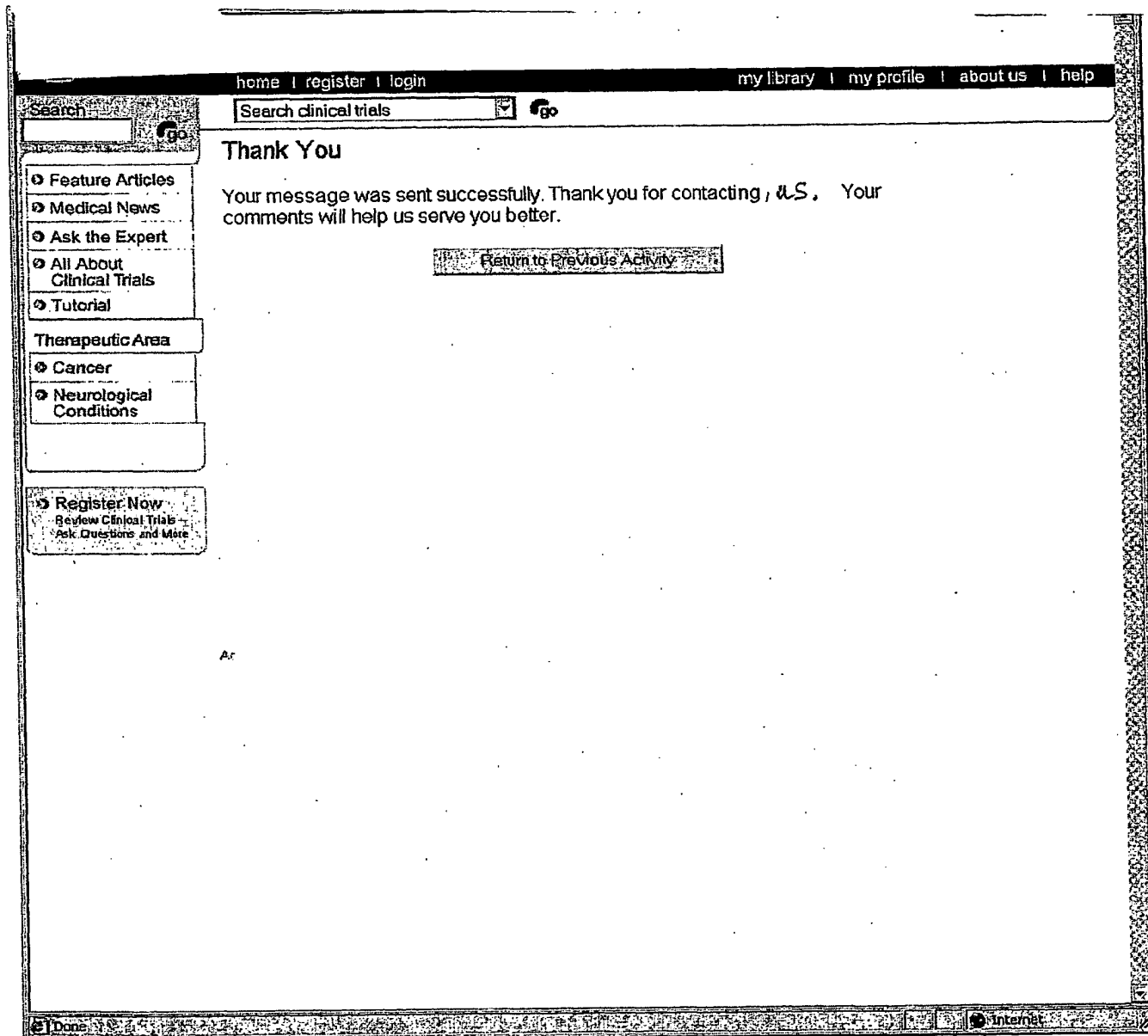


Fig- 6M



Search

Search clinical trials

Go

Home / Knowledge Center /

612

Feature Stories

News Archive

Ask the Expert

About Clinical Trials

Tutorial

Therapeutic Area

Cancer

Neurological Conditions

Register Now

Review Clinical Trials

Ask Questions and More

Welcome to My Library

Here's your chance to create a library of your very own. My Library is where you can store all kinds of information found throughout the site. Whether it's clinical trial information, abstracts on news articles, drug information, perspectives from our medical experts or personal stories, links to the items you select will be saved in this area for as long as you choose to keep them there. All you have to do is click the "Save to My Library" button found throughout the site.

In addition, you can type in personal notes along with the items you save. We will not access, use, or review your personal notes for any reason.

If you'd like to go directly to one of the five sections, select a link below:

News


Drug Information

Clinical Trials

Ask The Expert

Feature Stories

Do not show this page again.

FIG.  GN

BNSDOCID: <WO\_0155942A1\_1\_>

**Register**

./././ Investigator Questionnaire

### Investigator Questionnaire

Step 1 of 3

Thank you for your interest in joining our investigator database. The following questionnaire will take approximately one hour to complete. The privacy and security of your information is important to us. All information you submit is transmitted over a secure server. For more information, read our ..

Asterisks (\*) denote required fields.

**Last Name \***

**First Name \***

**Middle Name**

**Degree(s) \***

**Primary Research Facility's Organization or Institutional Name \***

**Street Address \***

**City \***

**State / Province / Region \***

**Country \***

**Zip Code / Postal Code \***

**Phone (with area code) \***

**Telephone Extension**

**Fax (with area code)**

**Email Address**

**Primary Specialty \***

**Board Certification(s) \*** ☐ Yes ☐ No

**Year of Certification**

**Board Eligible \*** ☐ Yes ☐ No

**Sub Specialty**

**Board Certification(s)** ☐ Yes ☐ No

**Year of Certification**

**Board Eligible** ☐ Yes ☐ No

**Number of years Investigator has participated in trials? \***

700

701

702

703

704

705

706

FIG. 7A

30/89

Indicate all phases of  
clinical  
research in which the  
Investigator participated  
\*

- ☐ Phase I ☐ Phase II  
☐ Phase III ☐ Phase IV

How many investigators  
conduct research at this  
PRF? \*

☐ Investigators

Is the Investigator  
affiliated with:  
(check all that apply)

- ☐ Local IRB ☐ Central IRB  
☐ IEC (Canadian sites only)

If affiliated with a local  
IRB, what is its name?

How often does the local  
IRB meet?

- ☐ Weekly ☐ Bi-weekly  
☐ Monthly ☐ As Needed  
☐ Other

If "other", frequency of  
local IRB meeting?

How soon after the IRB  
meeting will you receive  
an approval letter?

Has the Investigator  
ever been audited by  
the Food & Drug  
Administration (FDA) or  
any other regulatory  
agency?

☐ Yes ☐ No

1. If yes, what was the  
date of the audit?

Who was the auditor?

If audited, was a 483  
issued?

☐ Yes ☐ No

What were the results of  
the audit?

2. If yes, what was the  
date of the audit?

Who was the auditor?

If audited, was a 483  
issued?

☐ Yes ☐ No

What were the results of  
the audit?

FIG. 7B

31/89

Has the Investigator  
gone through an audit  
by a sponsor or CRO?

☐ Yes ☐ No

1. If yes, what was the  
date of the audit?

Who was the auditor?

What were the results of  
the audit?

2. If yes, what was the  
date of the audit?

Who was the auditor?

What were the results of  
the audit?

710

Is your PRF

☐ Single specialty

☐ Multi-specialty

If PRF is multi-specialty,  
indicate specialties. (one  
per line)

711

Is your facility part of

☐ Solo practice

☐ Group practice

Is the facility affiliated  
with a Site  
Management  
Organization (SMO)  
or research group?

☐ Yes ☐ No

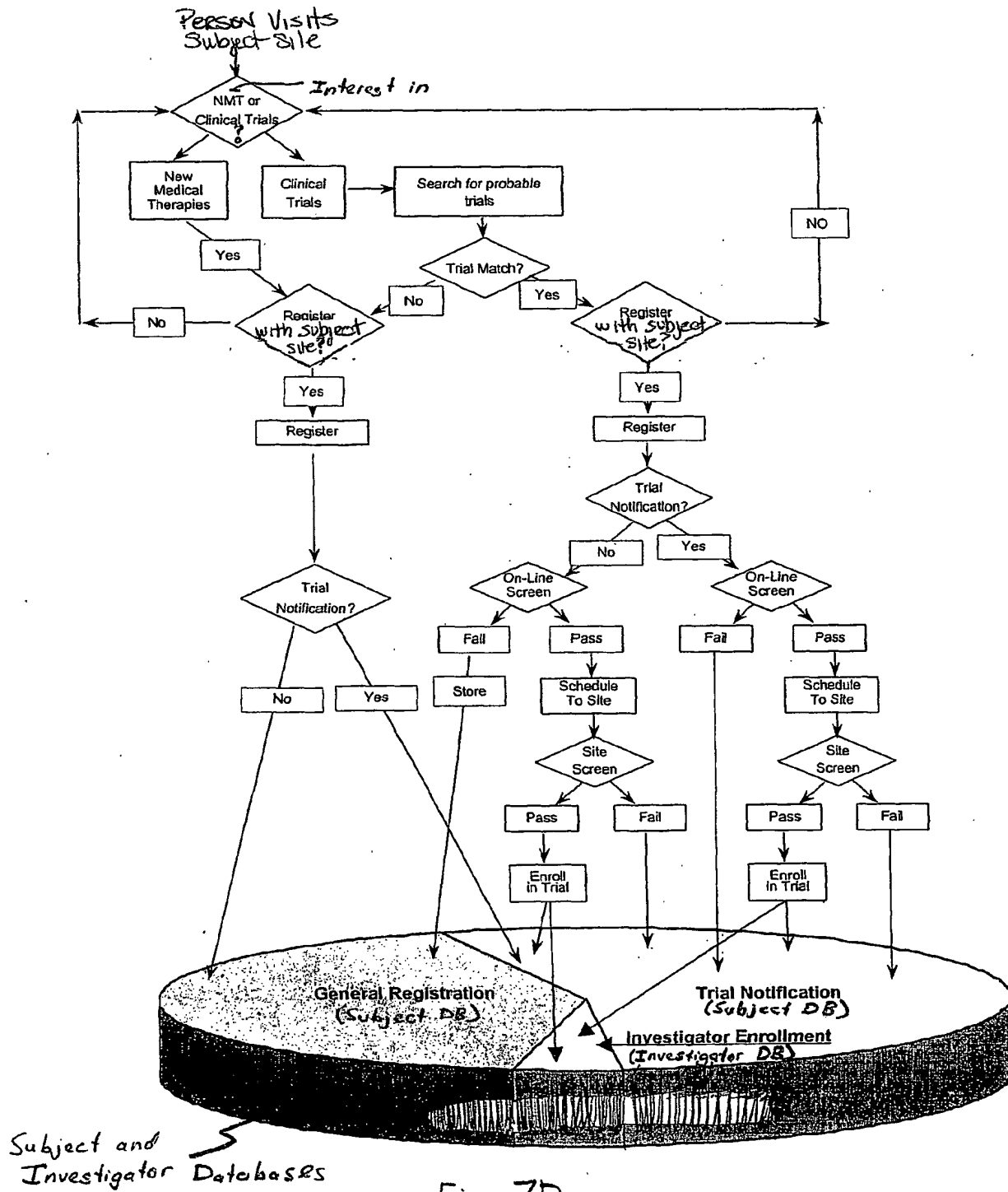
If affiliated, please  
specify the SMO name

If affiliated, is this an  
exclusive relationship?

☐ Yes ☐ No

. | . | . | . | .  
- | - | -

FIG. 7C



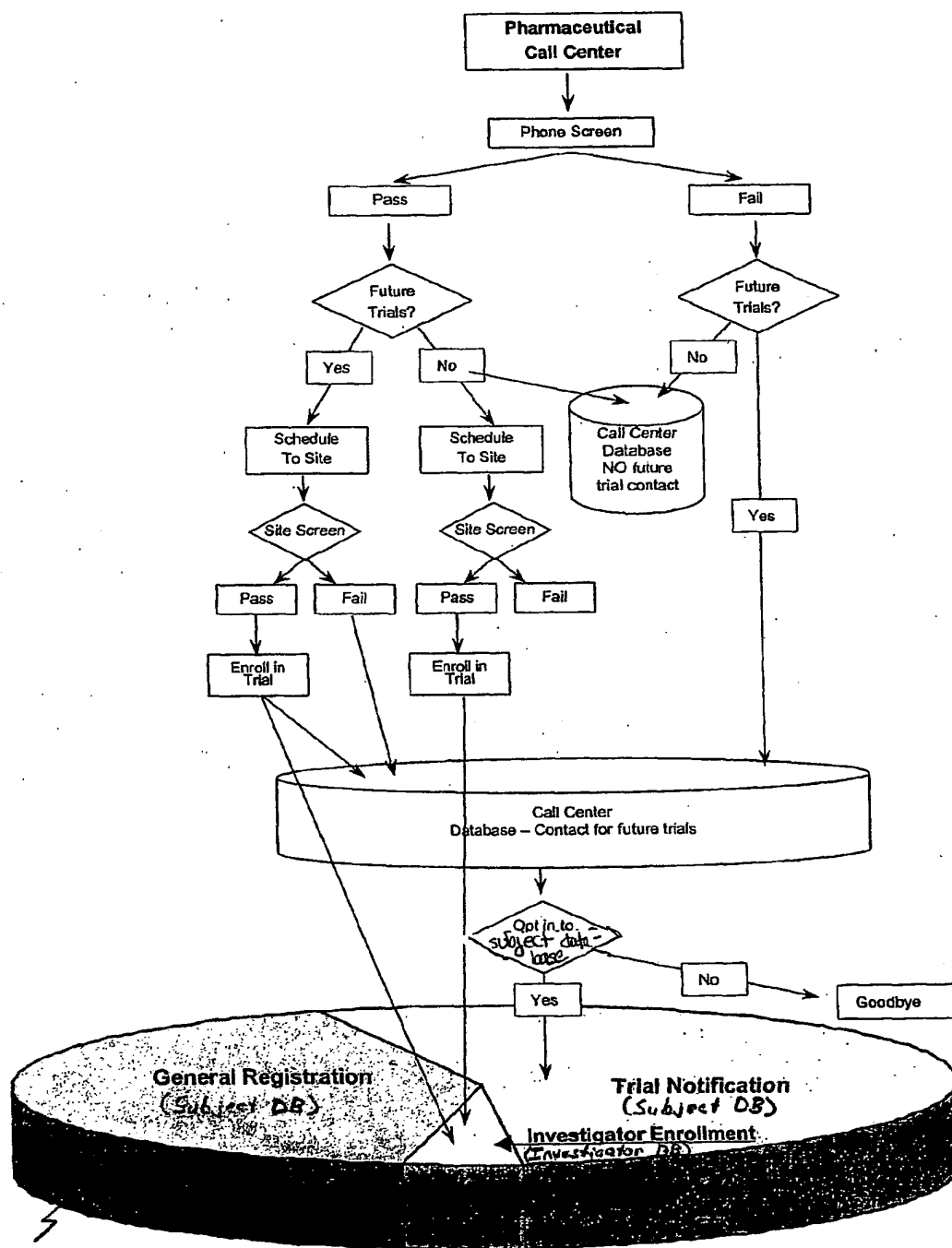


Fig. 7E

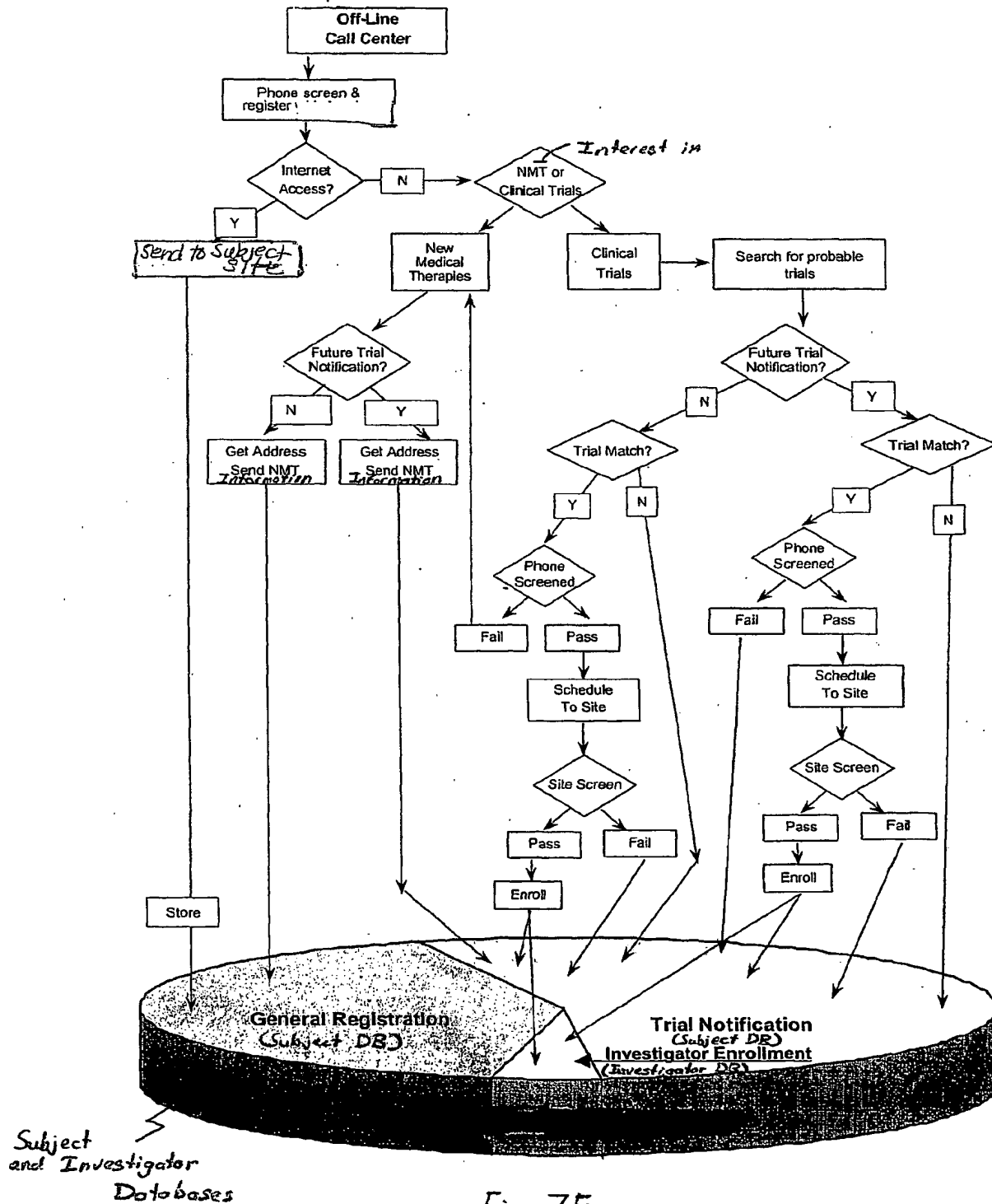


Fig. 7F

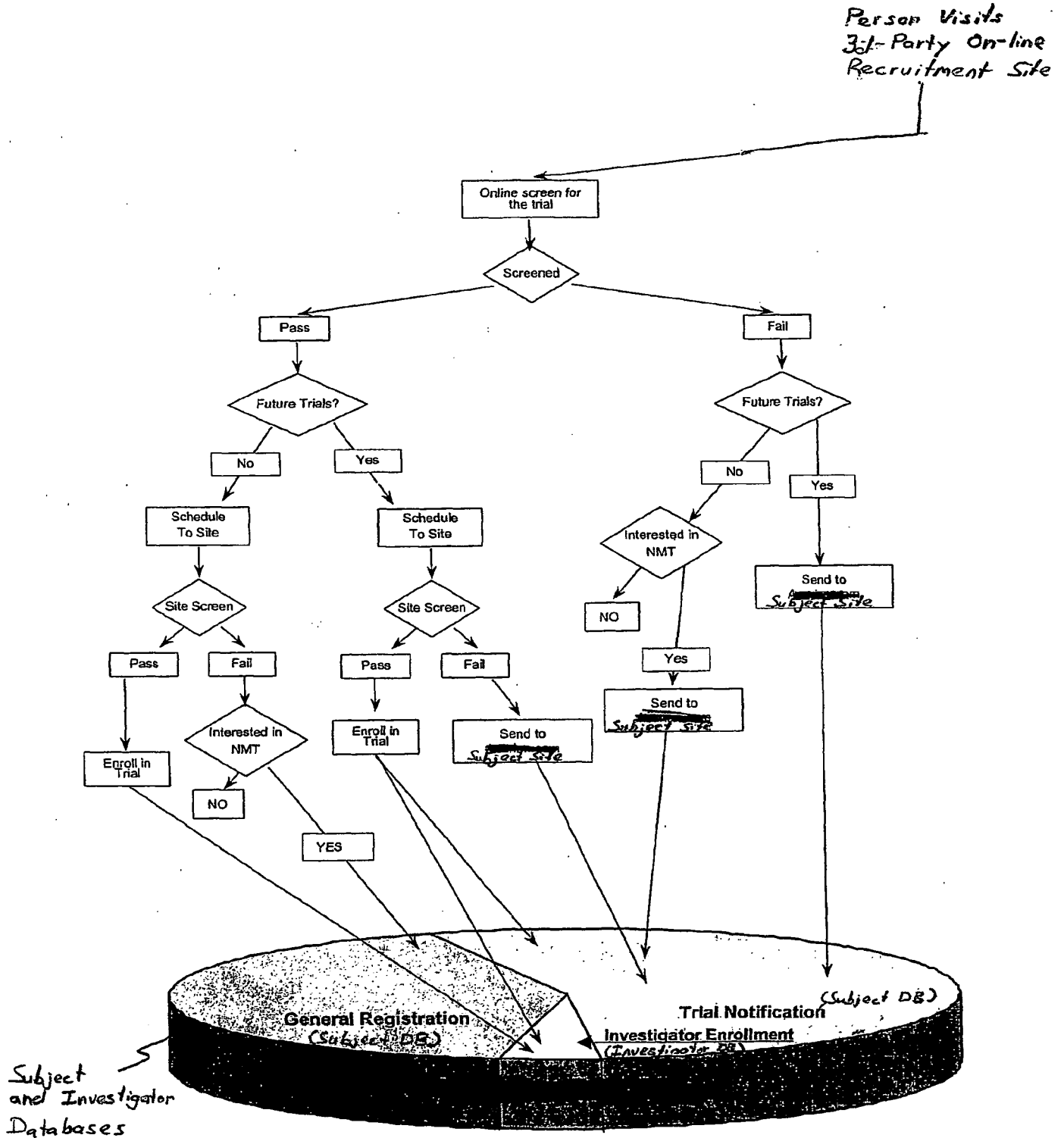


Fig 76



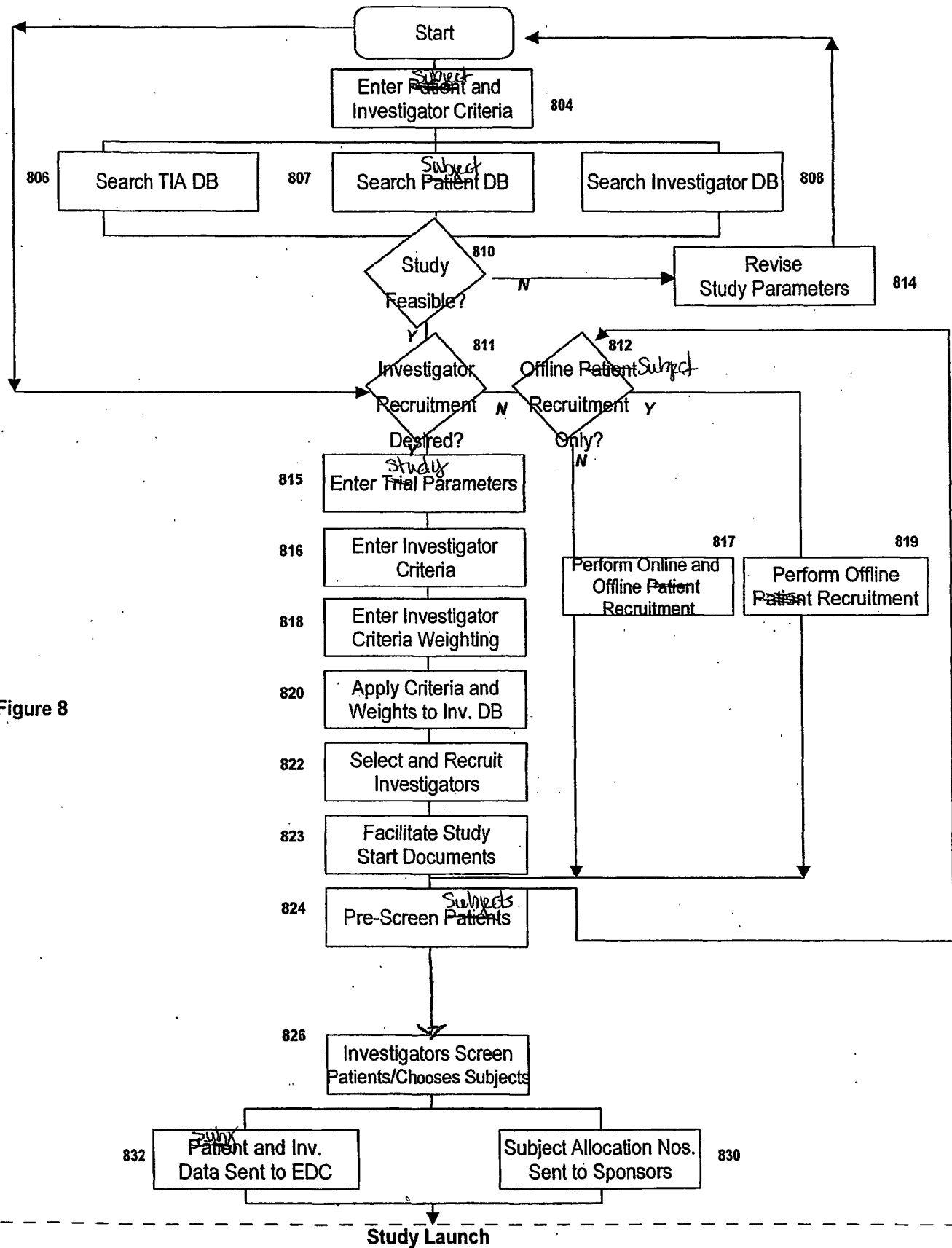


Figure 8

register

contact us help

Welcome

Home / Active Trials / Create Trial Parameters

Create Trial Parameters

To create an Active Trials files for a specific protocol please enter or select (from a drop down box) information to create trial parameters.

All fields required

Protocol Number

Protocol Title

Therapeutic Area

Disease Indication

Projected Number of Sites

Projected Number of Patients per Site

Projected Trial Start Date

Projected Trial Stop Date

Projected Enrollment Period (in months)

Trial Phase

--Select a Therapeutic Area--

--Select an Indication--

January 2000 (Month/Year)

January 2000 (Month/Year)

-- Select Trial Phase --

Save Trial

Save & Search for Investigators

Fig. 9

**Step 1:**

To identify potential investigators - please select a specialty.

Note: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections.

Adolescent Medicine  
Aerospace Medicine  
Allergy & Immunology

**Step 2:**

To include the prescribing behavior data in the investigator search results class relevant to the therapeutic area and indication. optional

Note: To select more than one drug class, point to the specialty and press control click. Limit of 2 selections.

No Drug Class  
Acne Therapy  
Aids Therapies  
All Other Misc. Ethical Drugs

**Step 3:**

To include the number of trials conducted by the investigator in the search a number. optional

1

**Step 4:**

To access additional databases to enhance the investigator selection process selections below. optional

Note: To select more than one patient disease indication encounter category, point to the specialty and press control click. Limit of 2 selections.

**Patient Therapeutic Area**  
[Dropdown menu]  
**Patient Disease Indication**  
[Dropdown menu]  
**Patient Disease Indication Encounter Category**  
-Select a Category-  
Case Load Estimates - Malignancy of hepatobiliary system of pancreas  
Inpatient Discharge Diagnosis - Malignant neoplasm of pancreas  
**Patient Distance from Site (in miles)**  
≤ 3

**Step 5:**

To limit search by geographical location- please enter your selections below

**Municipal Area**  
-Select a Municipal Area-

Fig. 10

### Investigator Search Results

The following Investigator search results reflect the investigator search criteria and the patient demographic data selected in the Investigator Search. Review selections by scrolling down this page or by clicking here: [Investigator Search Criteria Summary](#). Click a column heading to sort by that column.

Exhibit 1-20 out of 289

**Search Results:**

Spacility	City, State	Plant	Average Length of Stay - Angin.	Anticoagul.
Cardiovascular Disease	SEATTLE, WA	1	37 18-Average Length of Stay - Angin.	1-Anticoagul.
Cardiovascular Disease	LA JOLLA, CA	2	28 4-Average Length of Stay - Angin.	1-Anticoagul.
Cardiovascular Disease	SALT LAKE CITY, UT	3	27 5-Average Length of Stay - Angin.	3-Anticoagul.
Cardiovascular Disease	MILWAUKEE, WI	4	27 9-Average Length of Stay - Angin.	1-Anticoagul.
Cardiovascular Disease	CONCORD, NH	5	25 36-Average Length of Stay - Angin.	10-Anticoagul.
Cardiovascular Disease	MINNAPOLIS, MN	6	25 6-Average Length of Stay - Angin.	6-Anticoagul.
Cardiovascular Disease	OKLAHOMA CITY, OK	7	24 10-Average Length of Stay - Angin.	3-Anticoagul.
Cardiovascular Disease	PITTSBURGH, PA	8	22 27-Average Length of Stay - Angin.	1-Anticoagul.
Cardiovascular Disease	SEASIDE, CA	9	20 4-Average Length of Stay - Angin.	1-Anticoagul.
Cardiovascular Disease	HILLSBORO, OR	10	19 2-Average Length of Stay - Angin.	3-Anticoagul.
Cardiovascular Disease	PORT HURON, MI	11	18 5-Average Length of Stay - Angin.	1-Anticoagul.
Cardiovascular Disease	BALTIMORE, MD	12	16 27-Average Length of Stay - Angin.	9-Anticoagul.
Cardiovascular Disease	DURHAM, NC	13	16 6-Average Length of Stay - Angin.	5-Anticoagul.
Cardiovascular Disease	REDONDO BEACH, CA	14	15 10-Average Length of Stay - Angin.	3-Anticoagul.
Cardiovascular Disease	PEORIA, IL	15	13 33-Average Length of Stay - Angin.	5-Anticoagul.
Cardiovascular Disease	SAN FRANCISCO, CA	16	13 3-Average Length of Stay - Angin.	5-Anticoagul.
Cardiovascular Disease	CHARLESTON, SC	17	13 5-Average Length of Stay - Angin.	1-Anticoagul.
Cardiovascular Disease	BUFFALO, NY	18	12 4-Average Length of Stay - Angin.	5-Anticoagul.
Cardiovascular Disease	SELEERSVILLE, PA	19	12 3-Average Length of Stay - Angin.	10-Anticoagul.

Next 20's

Fig 11

register
contact us | help

Welcome

---

Protocol Number  
**345678**

- Register
- Services
- FAQ
- Document Summary
- Document View
- Investigator View

Home / [Active Trials](#) / [Trial at a Glance](#) / Document Tracking

### A multi-center study... Document Summary

Summary of document status for the selected protocol. Click on any document to go to Document View by Investigator. Click on any Investigator to go to specific Investigator Document View. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.

Roach/IRB
Regulatory
Financial
Vendor Info
CV / Signature
IRB
Misc

**Legend**

S = Sent

R = Received

C = Completed

Questionnaire	Conf. Agreement	Trial Synopsis	Other 1	Other 2	Other 3	Other 4	Other 5	Other 6	Other 7

**Investigator**

Smith, J.      S

Robinson, M.      D

**Investigators**

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

➔ Return to Trial at a Glance

Fig. 12:

BNSDOCID: <WO\_\_\_\_\_0155942A1\_I\_>

[register](#)[contact us](#)[help](#)

Welcome

Protocol Number  
**345678**

[Register](#)  
[Services](#)  
[FAQ](#)  
[Document Summary](#)  
[Document View](#)  
[Investigator View](#)

[Home](#) / [Active Trials](#) / [Trial at a Glance](#) / [Document Tracking](#) / [Document View by Investigator](#)

### Document View by Investigator

Summary of document status by investigator. Click on any investigator to go to document history of the document selected in the drop down box. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.

[Consent](#)[Regulatory](#)[Financial](#)[Vendor Info](#)[CV / Signature](#)[IRB](#)[Misc](#)

Document: [Questionnaire](#)

[Create New Document](#)

Investigator	Date Sent	Date Rec'd	Date Completed
Smith J	1/27/01	1/27/01	1/28/01

Investigator:  
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

FIG 13

**From:** Service Provider

**Sent:** June 6, 2000

**To:** Ms. Moore

**Subject:** Clinical Trial Opportunity

Dear Ms. Moore:

You may qualify for an upcoming clinical trial opportunity. For additional information go to [https://www.website.com/study/zz-234567-22\\*](https://www.website.com/study/zz-234567-22*) and complete the study specific questionnaire.

Contact [service.com](http://www.service.com) with any questions or comments you may have.

Sincerely,

Service Provider

If you have received this message in error or no longer would like to be considered or contacted about clinical trials please go to <http://www.service.com/remove>

Fig. 14

## Questionnaire — Alzheimer's

In order to evaluate whether you may be eligible for this study, we will need to review some of your medical history. Are you legally able to provide us with this information for the potential study participant?

Yes, I am the potential study participant

Yes, I am a caregiver for the potential study participant with the ability to provide the potential participant's information for the purpose of seeking enrollment in clinical studies

No, I am not legally able to provide this information.

In answering the following questions, "you" or "your" refers at all times to the potential study participant.

Please provide your gender.

- ☐ Male
- ☐ Female

How did you hear about this study?

- ☐ Internet
- ☐ Newspaper Ad
- ☐ Newspaper Article
- ☐ Radio Ad
- ☐ Radio Public Service Announcement
- ☐ TV Ad
- ☐ TV program
- ☐ Physician
- ☐ Friend
- ☐ Support Group
- ☐ Patient Ed Materials
- ☐ Cardiology Newsletter
- ☐ Other, please specify: \_\_\_\_\_

The purpose of this medical research study is to evaluate the effect of an investigational drug on the ability to reason, remember, imagine, and learn in humans who have already been diagnosed with mild to moderate probable Alzheimer's Disease. You must live with a caregiver or receive daily visits from a responsible caregiver. The caregiver must be familiar with your recent medical history and be willing to come to 7 doctor visits for a period of 6 months.

After these questions are answered we may be able to refer you to a research site for further screening. After the site reviews your responses to the screening questions, a nurse or other person at the research facility will be calling you. At that time, it will be determined if a first visit should be scheduled to determine whether this study is appropriate for you.

Have you been diagnosed with Alzheimer's disease?

- ☐ Yes
- ☐ No

Have you experienced a deterioration in memory over at least the last 6 months?

FIG. 15A



## Questionnaire – Alzheimer's

- ☐ Yes
- ☐ No

Click the box next to the following if you have experienced a decline in any of the following in at least the last 6 months:

- ☐ orientation
- ☐ judgement
- ☐ problem solving
- ☐ functioning in community affairs
- ☐ functioning in home or hobbies
- ☐ functioning in personal care

Do you live in a residential home?

- ☐ Yes
- ☐ No

Click the box next to the person who will serve in the role of Caregiver:

- I am the Caregiver
- Friend
- Relative
- Paid personnel
- No Caregiver

1. Please enter your date of birth:

Day      Month      Year (pull-down boxes)

- ☐ If female, continue with question 2
- ☐ If male, continue with question 6

2. Are you / Is (Patient) surgically sterile or post-menopausal for 1 year or more?

- ☐ Yes – continue with question #6
- ☐ No – continue with question #3

3. Do you / Does (Patient) have any other neurological conditions such as:

- ☐ Parkinson's disease
- ☐ Pick's disease
- ☐ Huntingtons chorea
- ☐ Down's syndrome
- ☐ Creutzfeldt-Jacob disease
- ☐ Other \_\_\_\_\_

4. Do you now or did you at any time, have one or more of the following conditions resulting in your memory or *cognitive* impairment:

FIG. 15B

## Questionnaire – Alzheimer's

- ☐ Major head injury
  - ☐ Injury caused by trauma such as boxing
  - ☐ Vitamin deficiency
    - ☐ Type [drop down menu]
  - ☐ Brain abscess
  - ☐ Syphilis
  - ☐ Meningitis
  - ☐ AIDS
  - ☐ Brain cancer
  - ☐ Thyroid, parathyroid, or pituitary disease
  - ☐ Cushing's syndrome
  - ☐ Kidney failure
  - ☐ Uncontrolled diabetes
  - ☐ Mental retardation
5. Do you have a history of any of the following:
- ☐ Stroke within the past 12 months
  - ☐ Epilepsy or convulsions (Childhood convulsions caused by fever continue)
  - ☐ Major depression
  - ☐ Stomach ulcer that is currently being treated
  - ☐ Liver, kidney, or lung disease
  - ☐ Kidney stones
6. Have you had a heart attack or coronary artery bypass graft surgery within the past 6 months?
- ☐ No
  - ☐ Yes
7. Do you experience angina (chest pain) that required a change in medication in the past 3 months?
- ☐ Yes
  - ☐ No
8. Has a doctor told you that you have a heart rate that is slow or less than 50 beats per minute?
- ☐ Yes
  - ☐ No
9. Do you take medication for high blood pressure or chronic low blood pressure?
- ☐ Yes
    - ☐ Medication(s) taken: [drop down menu]
  - ☐ No
  - ☐ Don't know

F16. 15C

## Questionnaire – Alzheimer's

10. Do you take any medications for the purpose of treating memory loss such as dementia?
- ☐ Yes
  - ☐ No
11. Are you allergic to any medications?
- ☐ Yes
    - ☐ Which Medication(s) [drop down menu]
  - ☐ No
12. Are you taking any other medications including vitamins or herbal supplements such as Ginkgo Biloba?
- ☐ Yes
    - ☐ Which Medication(s) [drop down menu]
  - ☐ No
13. Have you ever been enrolled in a research study for galantamine?
- ☐ Yes
  - ☐ No
  - ☐ Don't know
14. Have you taken an investigational drug in the past 30 days or are you taking one now?
- ☐ No, I have not taken an investigational drug in the past 30 days
  - ☐ Yes, I have taken an investigational drug in the past 30 days
  - ☐ Yes, am taking an investigational drug now
15. How many drinks do you consume in a typical 24-hour period?
- ☐ 1-2 drinks
  - ☐ 3-5 drinks
  - ☐ 6-8 drinks
  - ☐ more than 8 drinks
16. Have you/patient had a CT scan or MRI of the head during the last 12 months?
- Yes
- No

FIG. 15D

Questionnaire – Alzheimer's

**SCREEN #2: PATIENT NOT ELIGIBLE FOR STUDY**

We appreciate your interest in this study. Unfortunately, from the information you have provided, you are not a candidate for participation in this study. May we have your permission to contact you in the future with information about this or other studies?

- ☐ Yes, contact me.
- ☐ No, I do not want to be contacted.

FIG. 15E

Questionnaire – Alzheimer's

SCREEN #3: PATIENT POTENTIALLY ELIGIBLE FOR STUDY:

Based on your responses, you may be eligible for the clinical study. We will forward this information to the research site you selected. The research site will contact you shortly to ask you further questions about your health, and possibly to schedule an appointment for the first visit. In the meantime, we will send you a Welcome Kit that contains information about the study. If the site does not contact you within 5 – 7 business days, please feel free to call the number that will be included in your mailed materials.

In the event that you do not participate in this particular study, may we have your permission to contact you in the future about other studies?

- ☐ Yes, contact me
- ☐ No, I do not want to be contacted

FIG. 15F

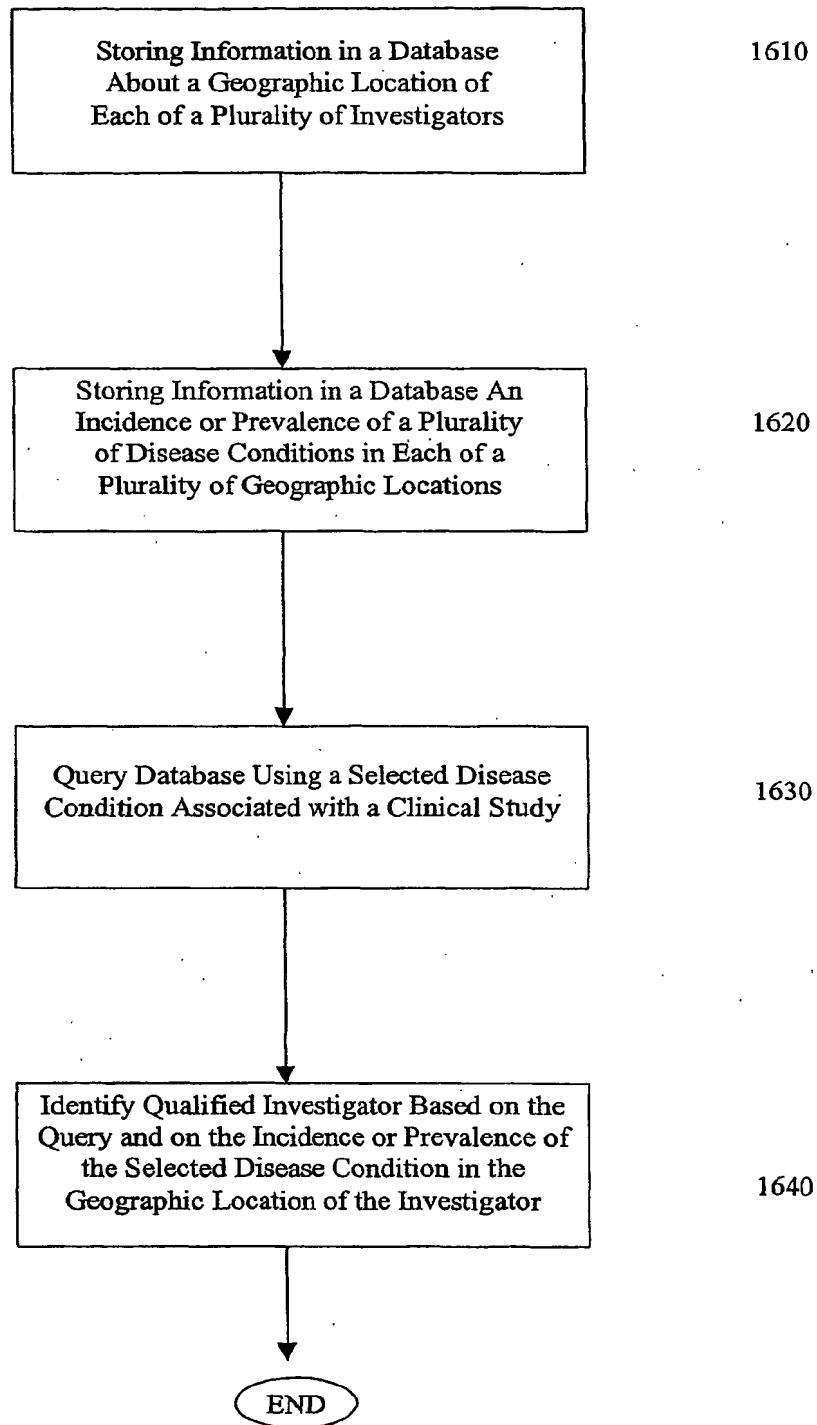


FIG. 16

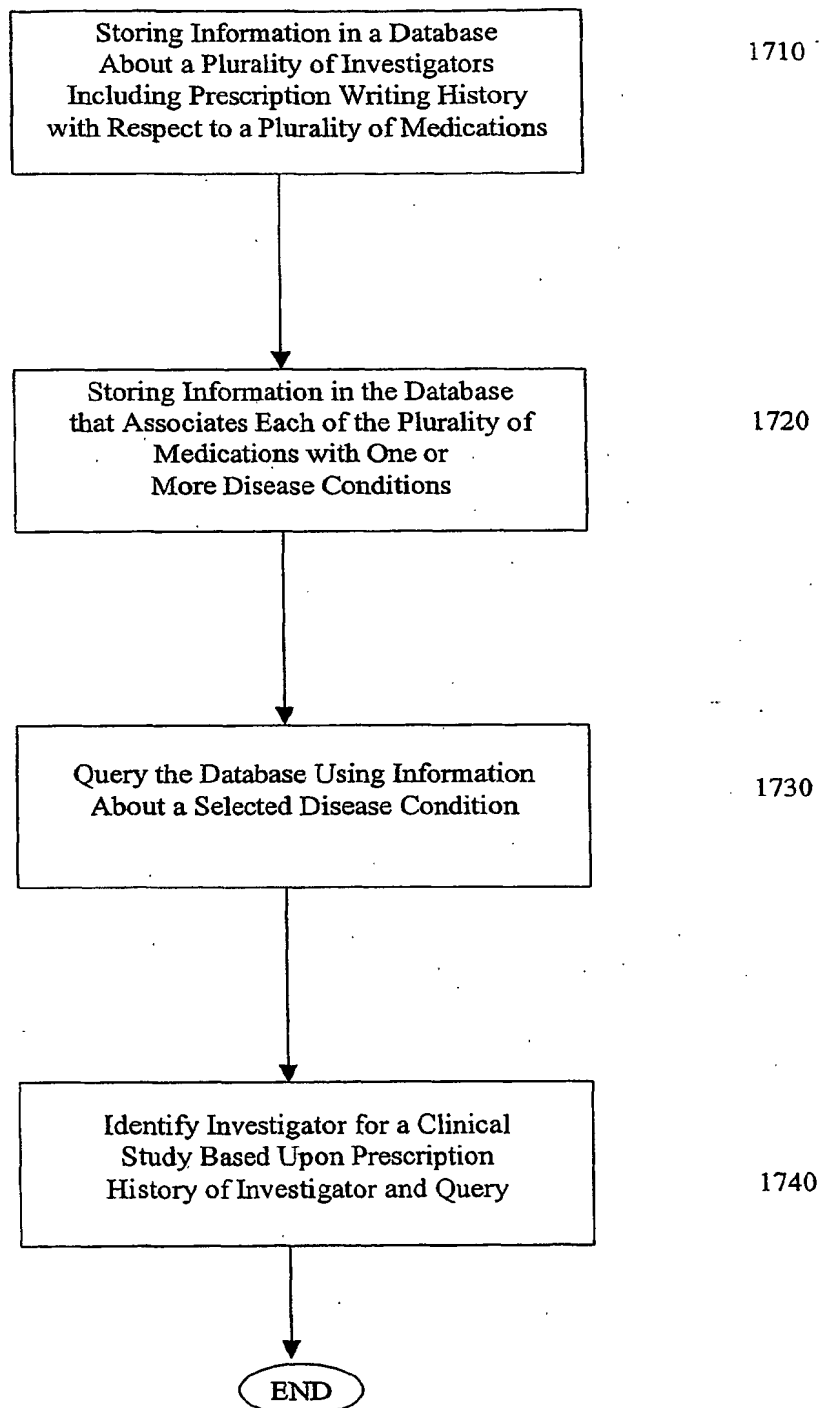


FIG. 17

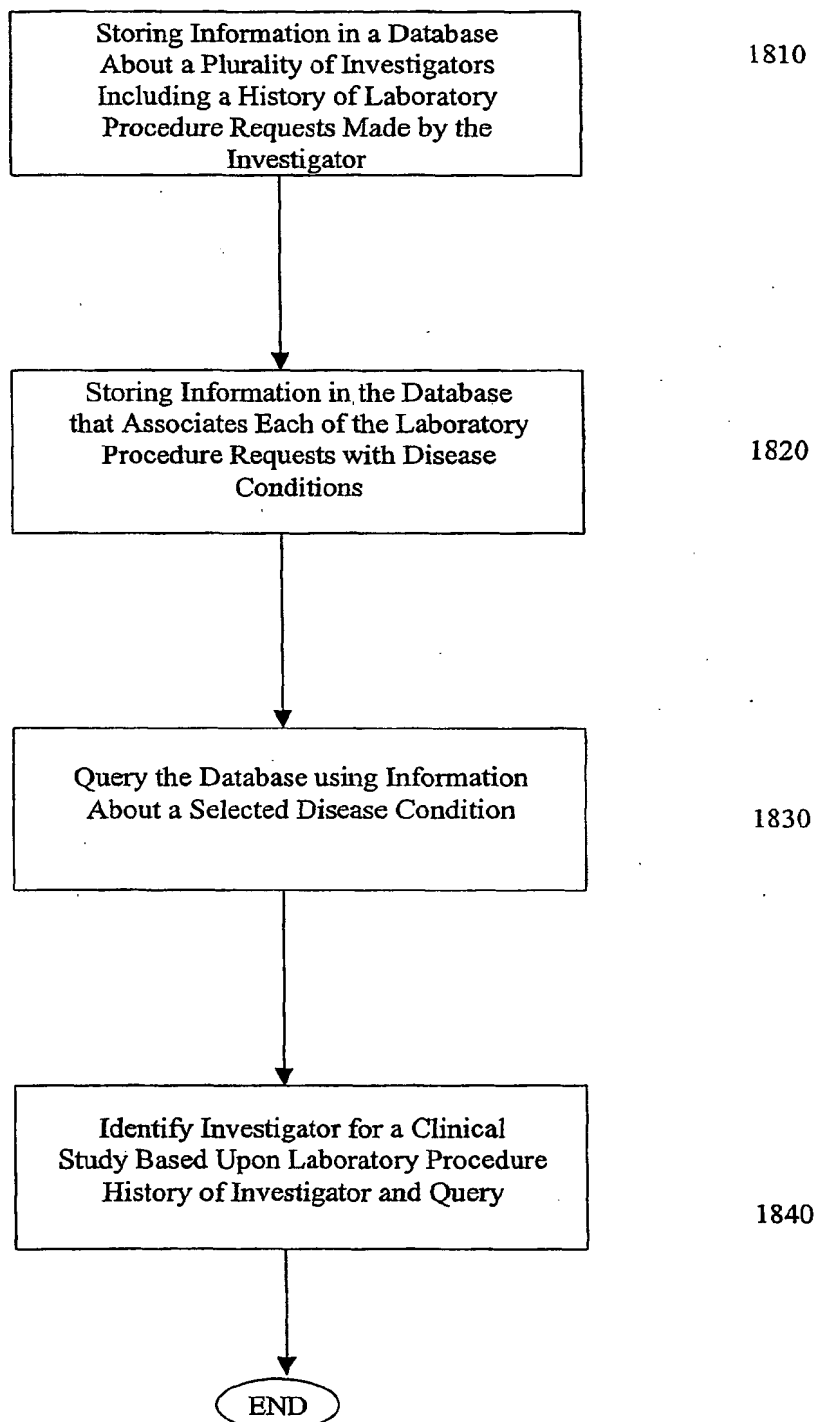


FIG. 18



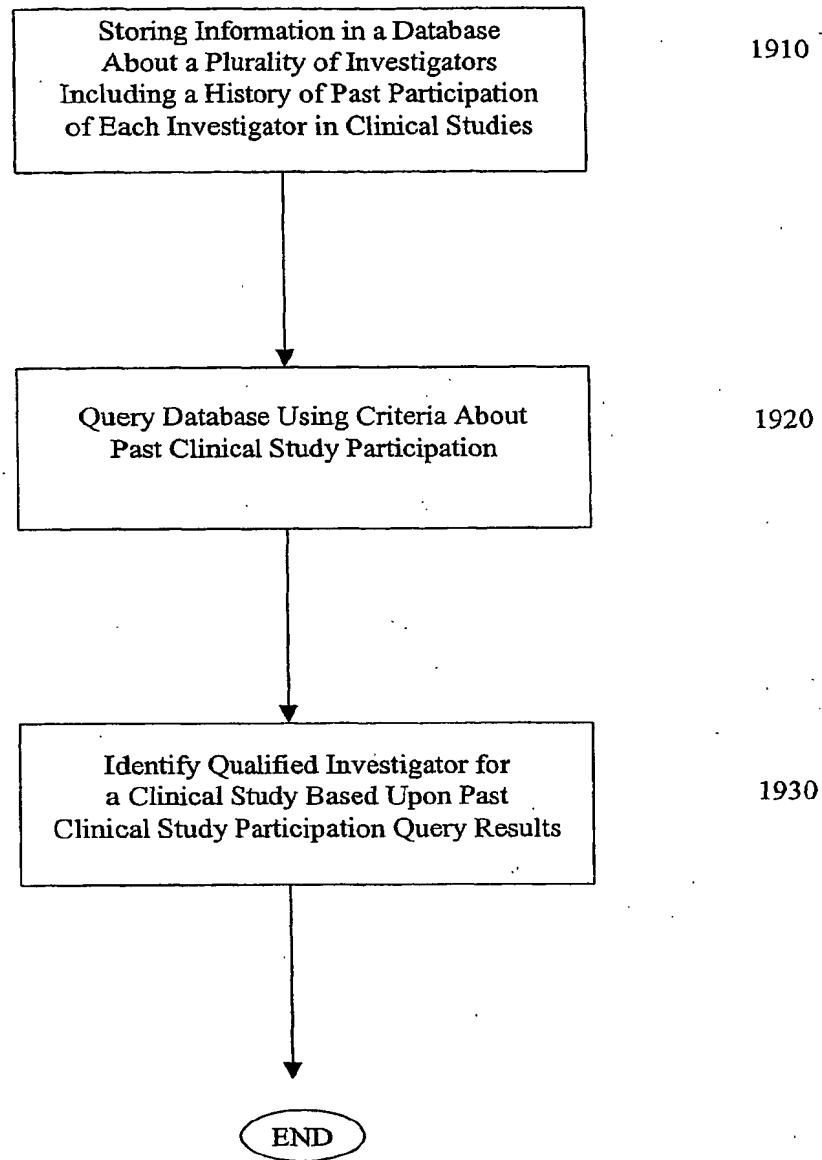
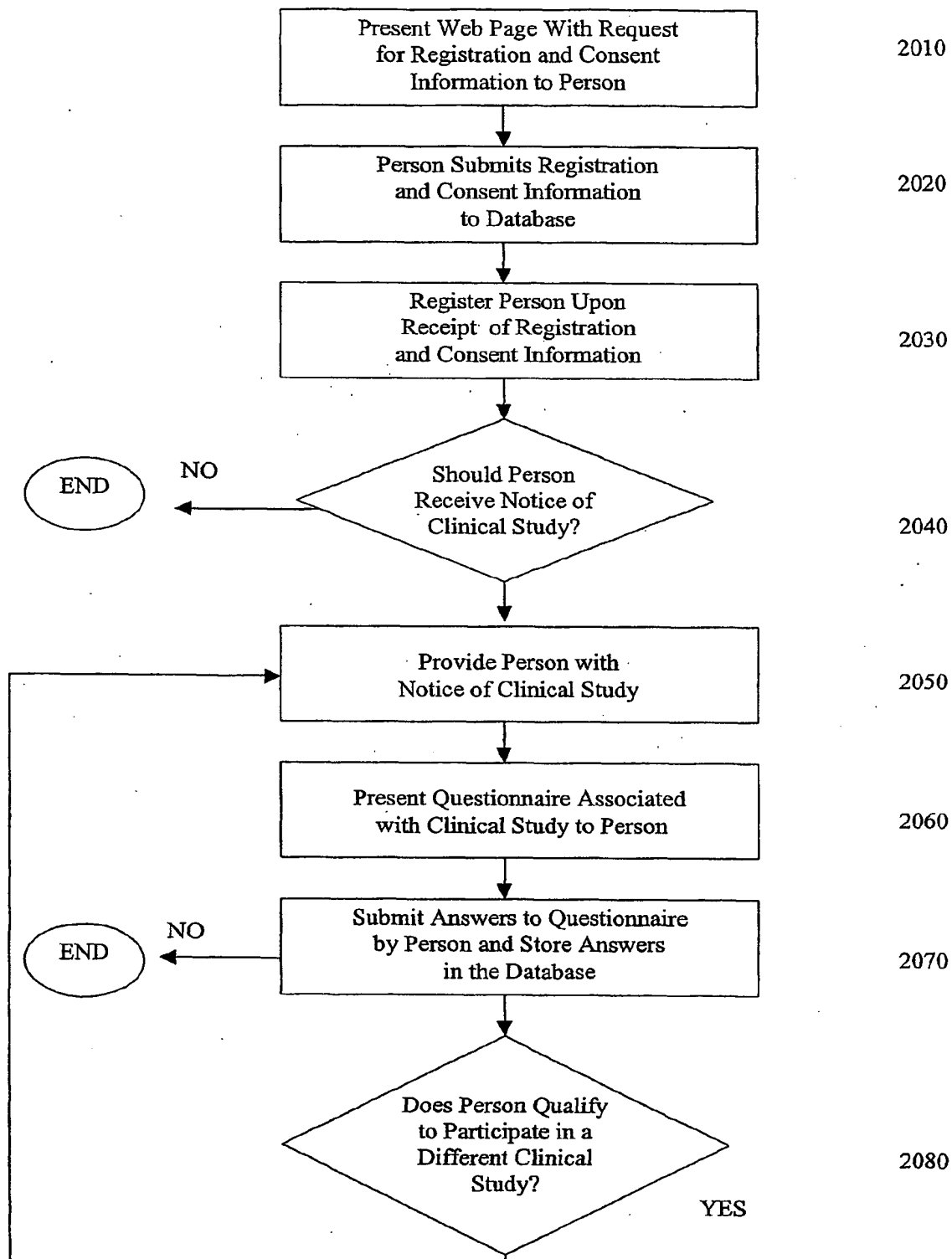


FIG. 19

FIG. 20



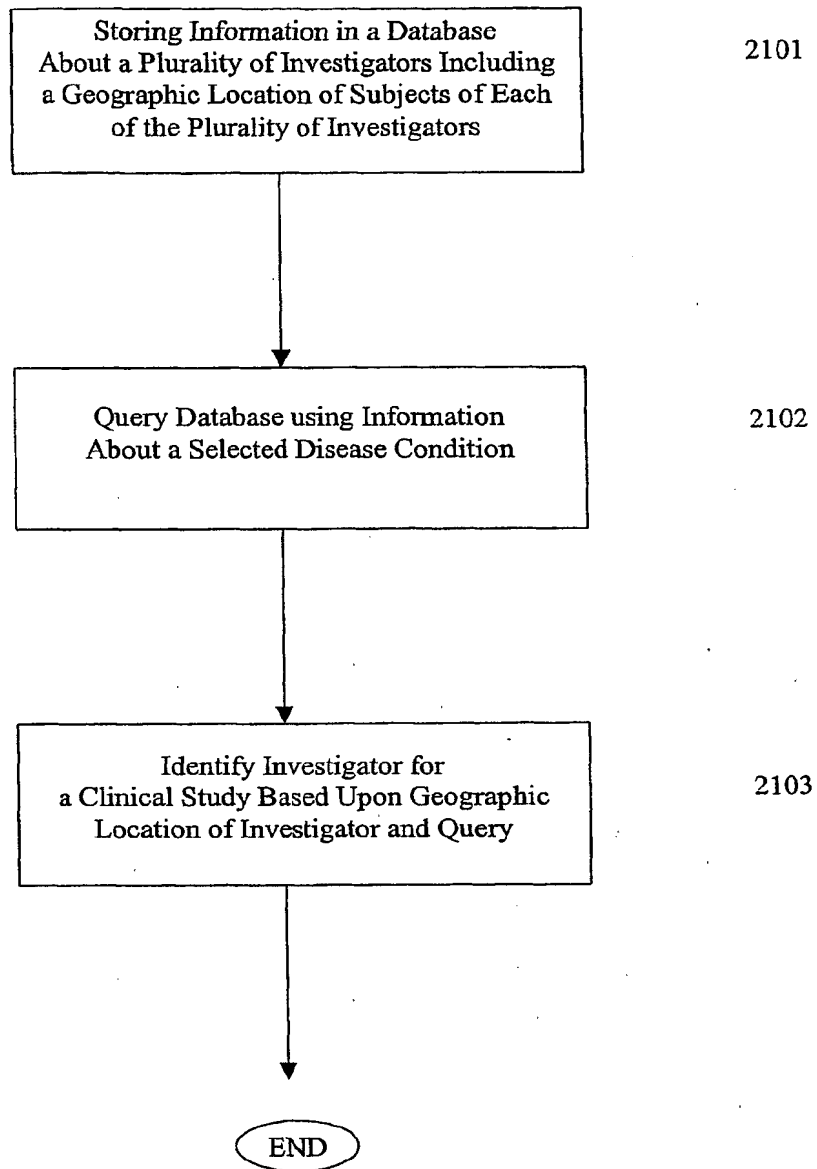


FIG. 21A

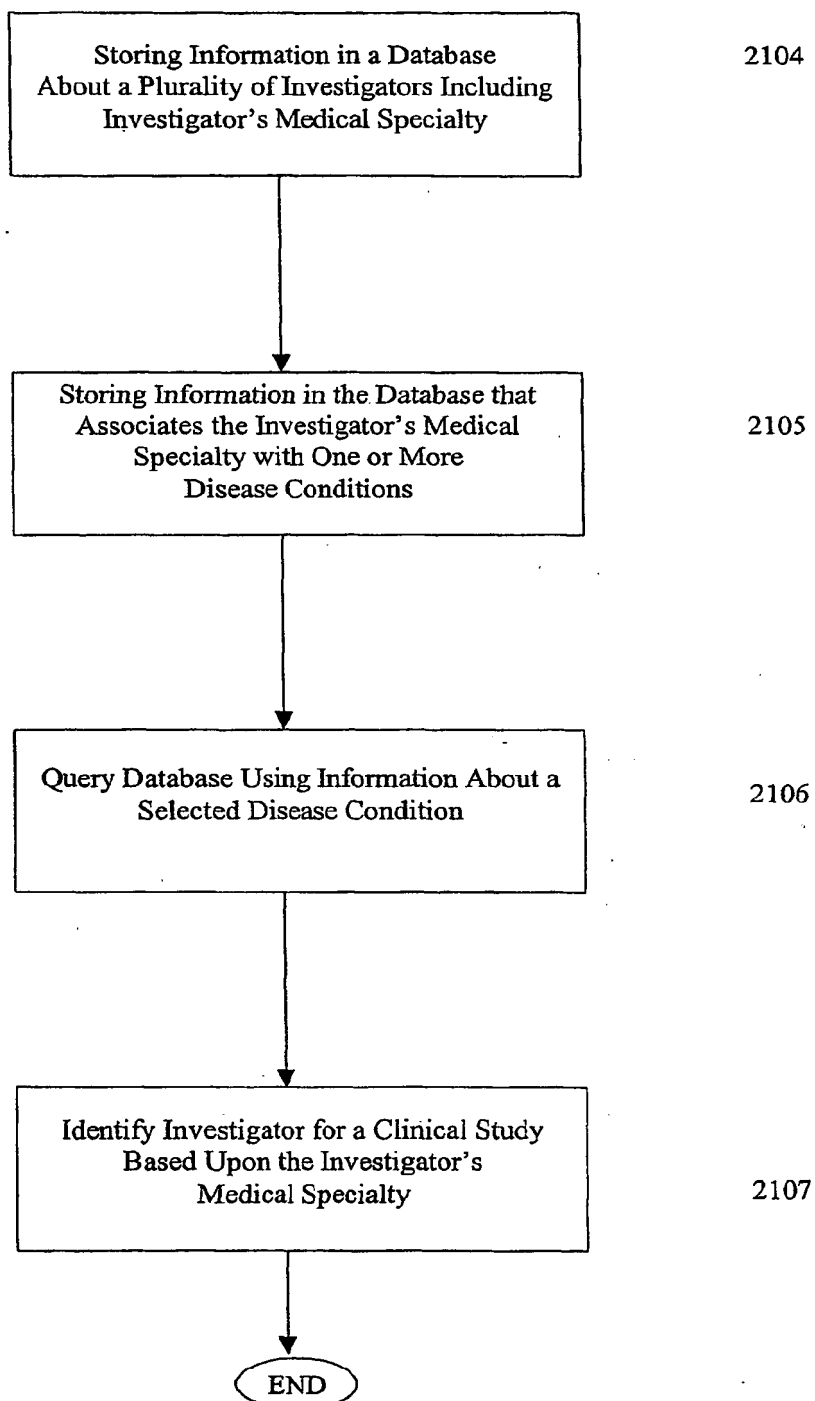


FIG. 21B

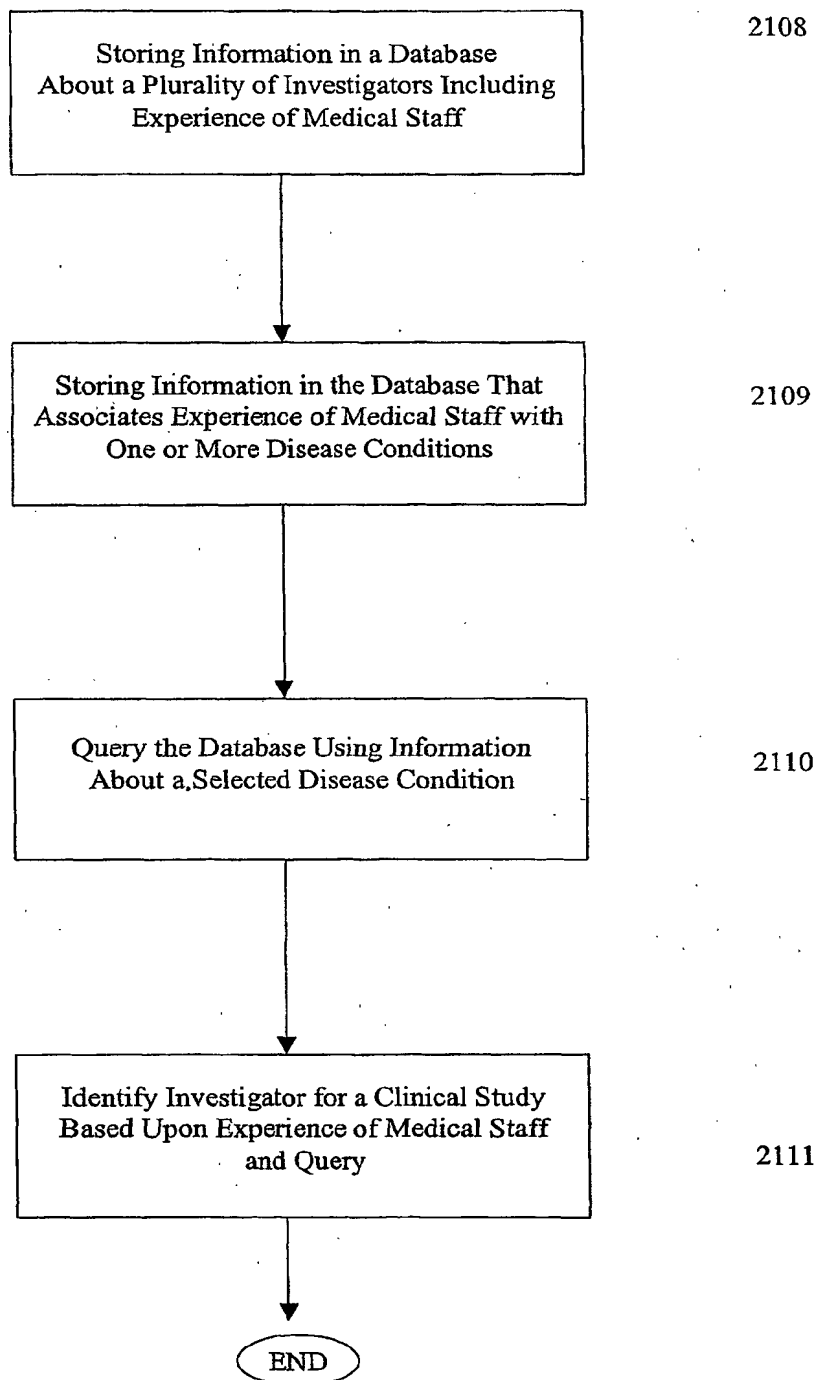


FIG. 21C

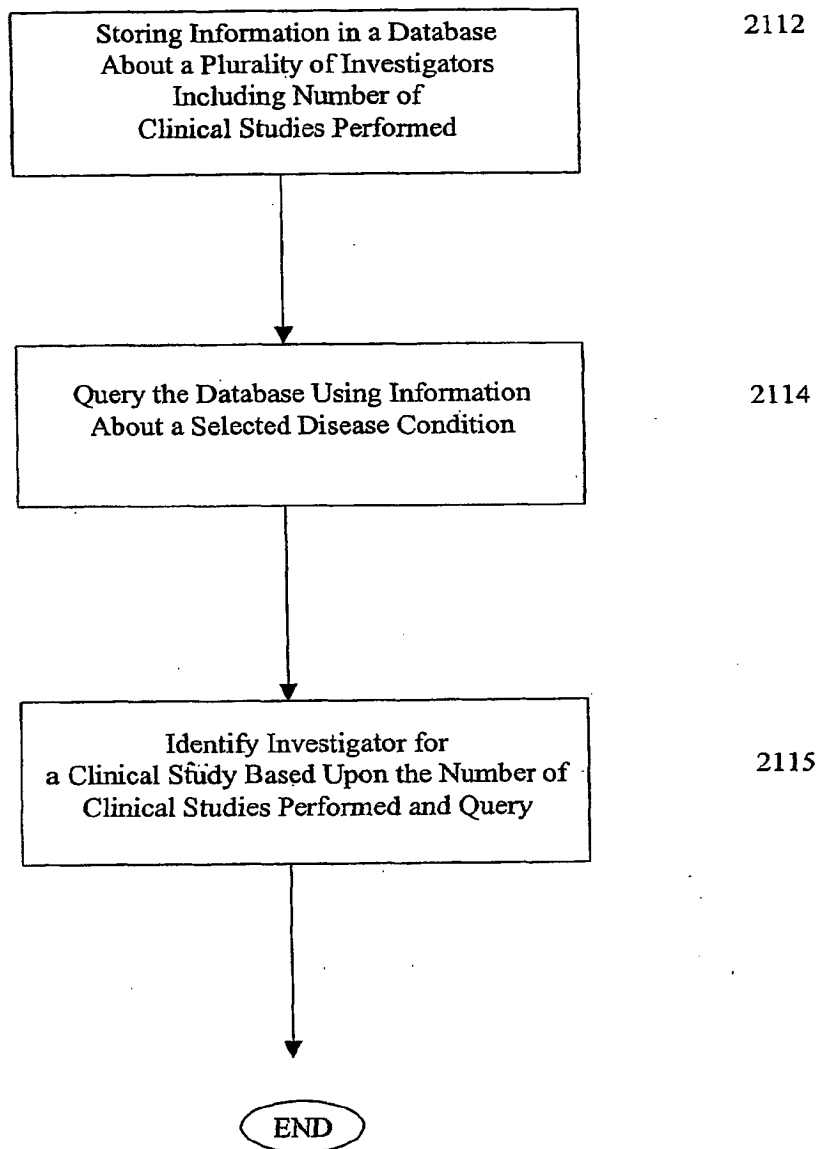


FIG. 21D

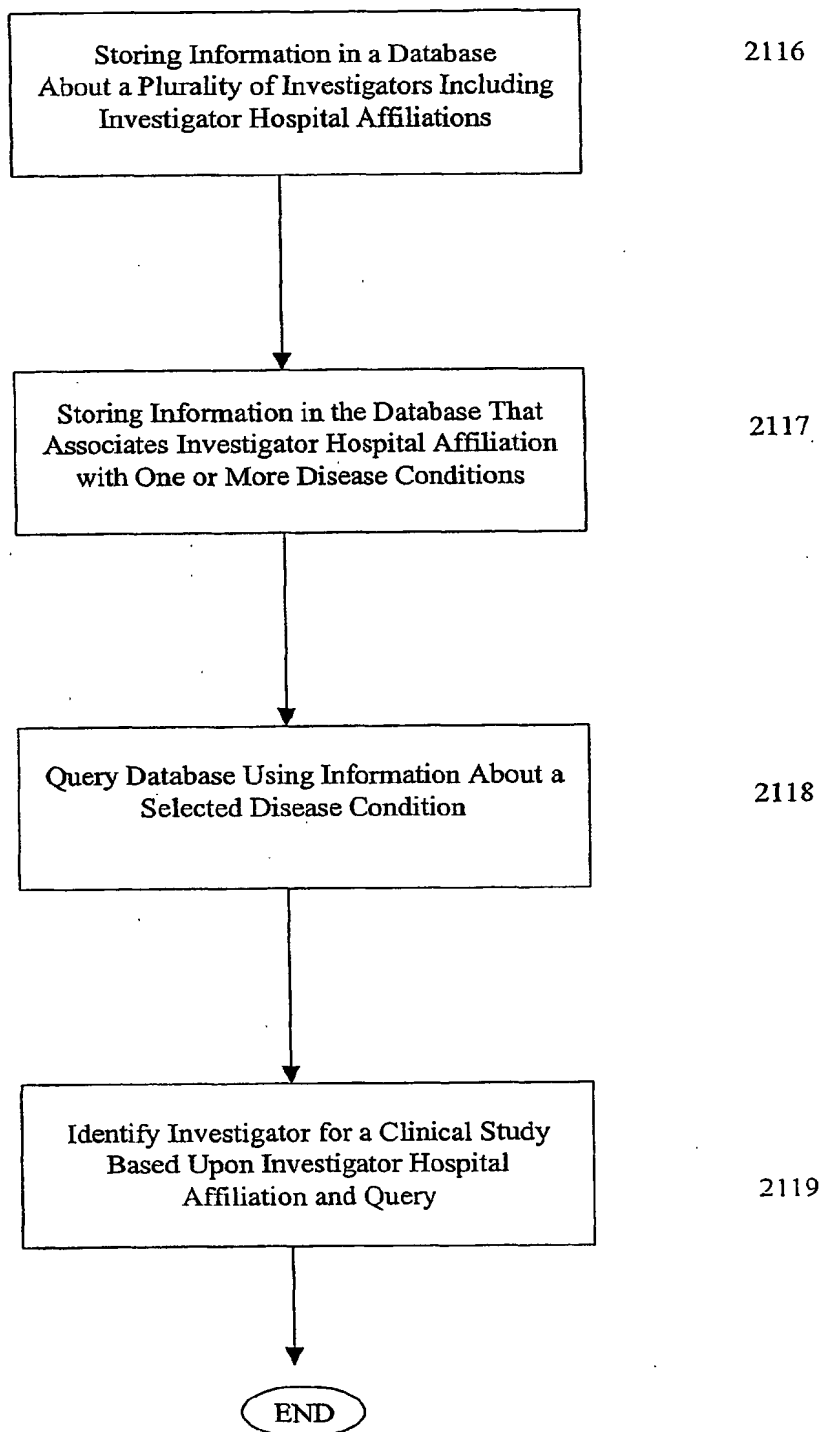


FIG. 21E

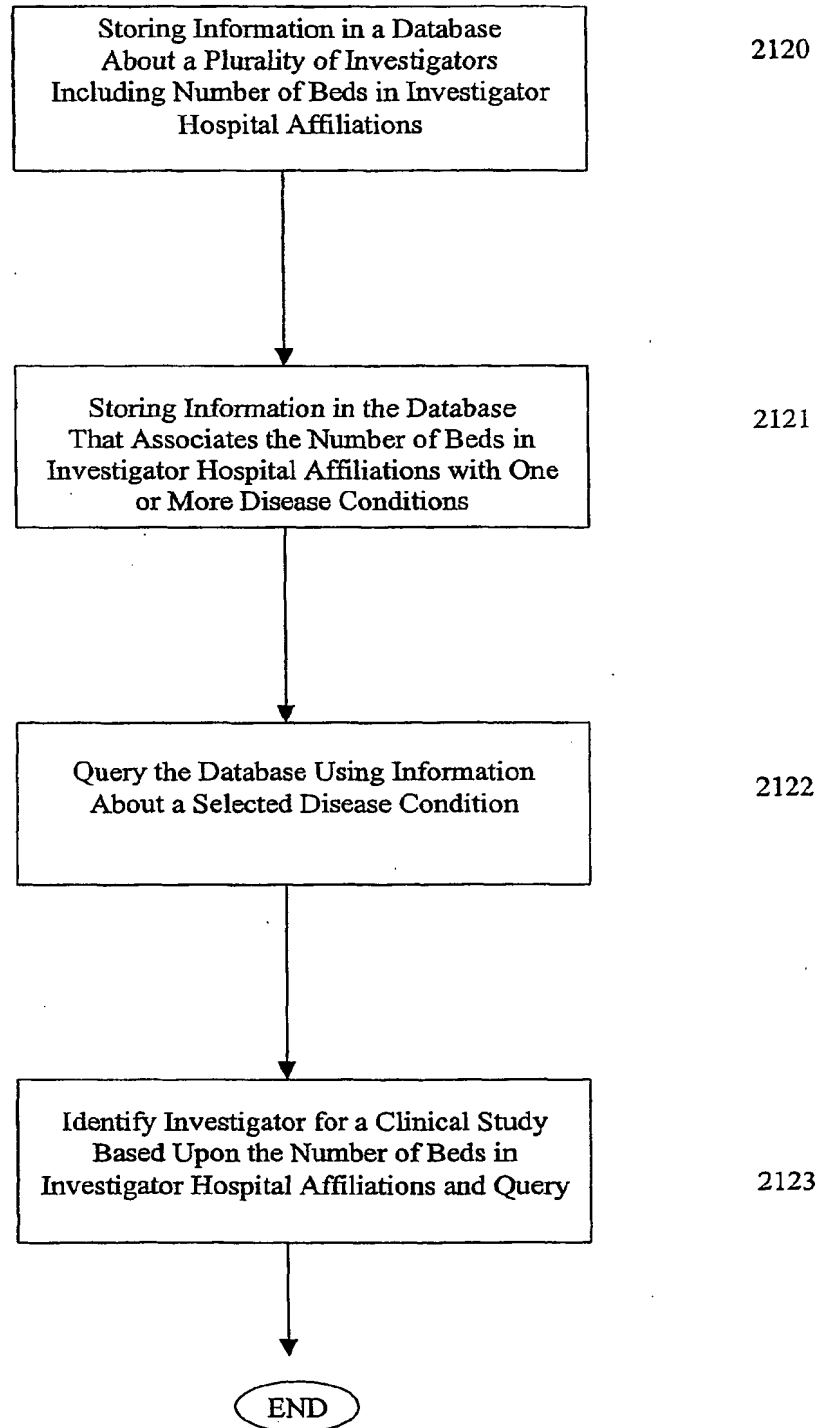


FIG. 21F



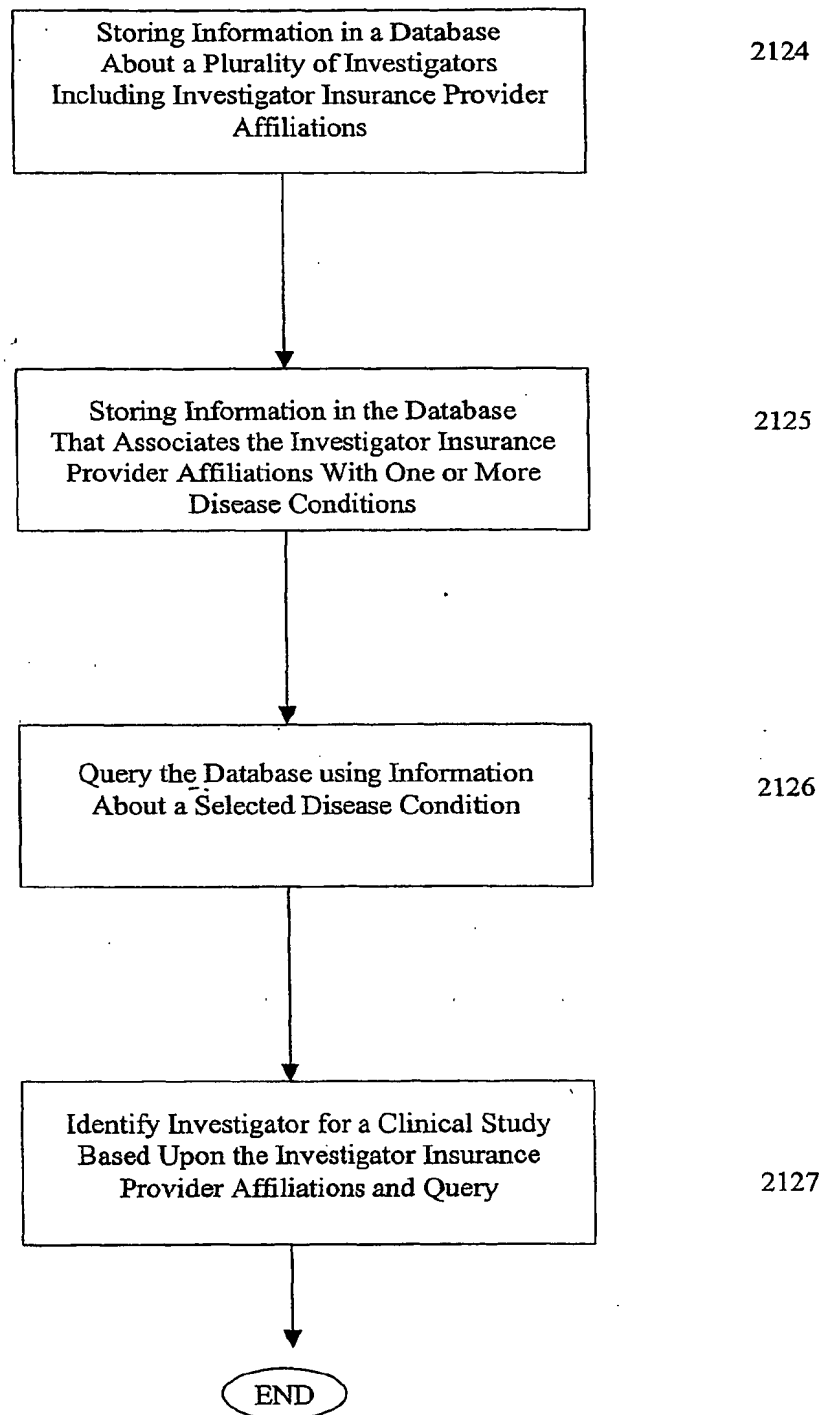


FIG. 21G

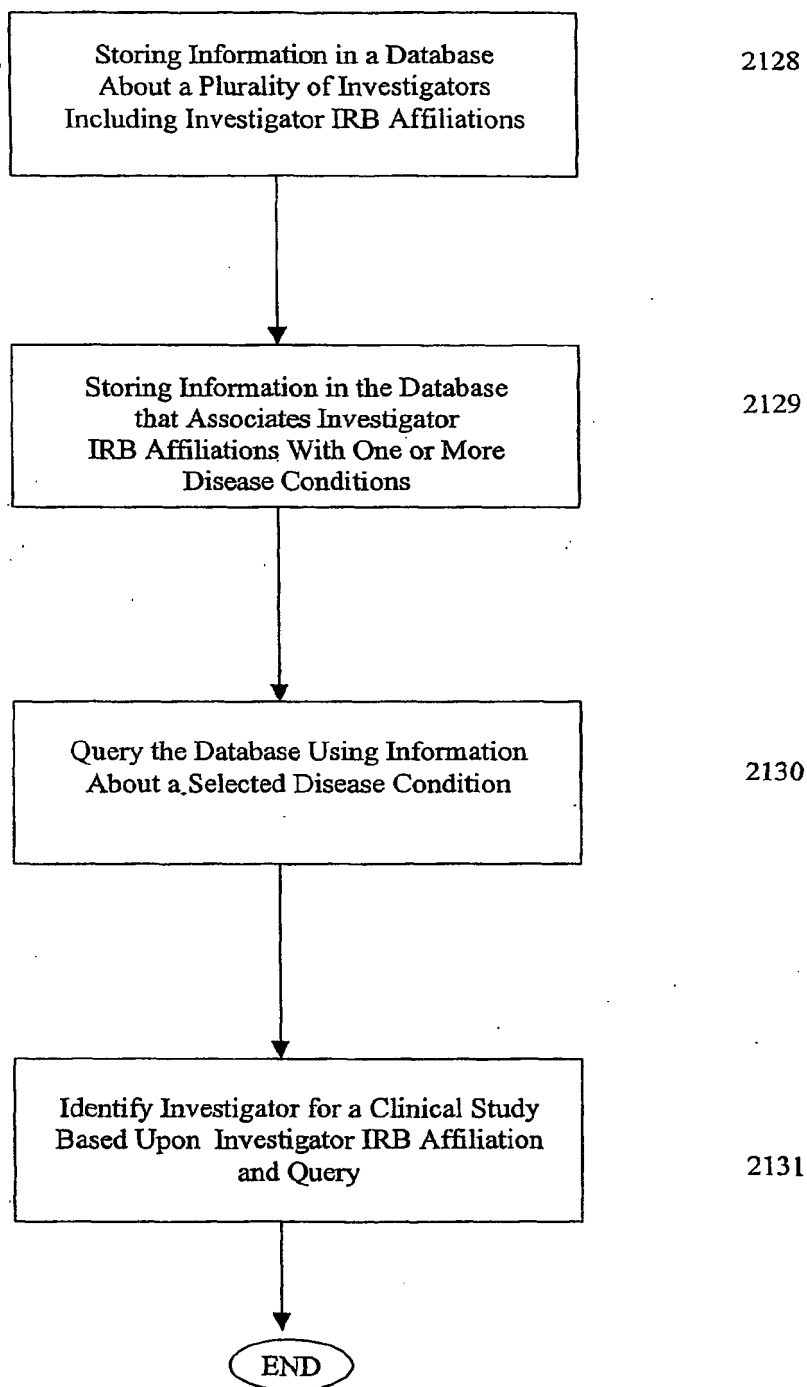


FIG. 21H

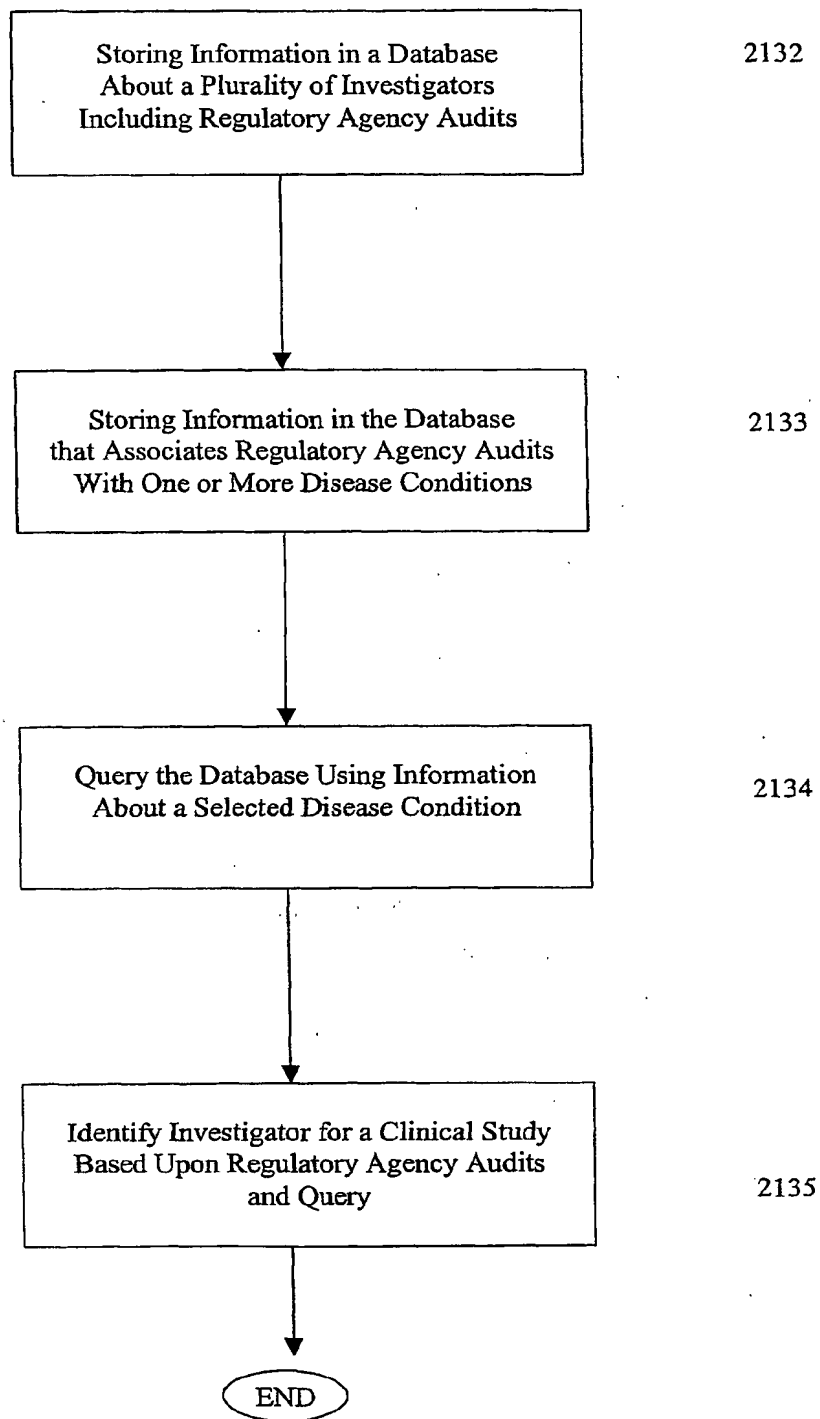


FIG. 21I

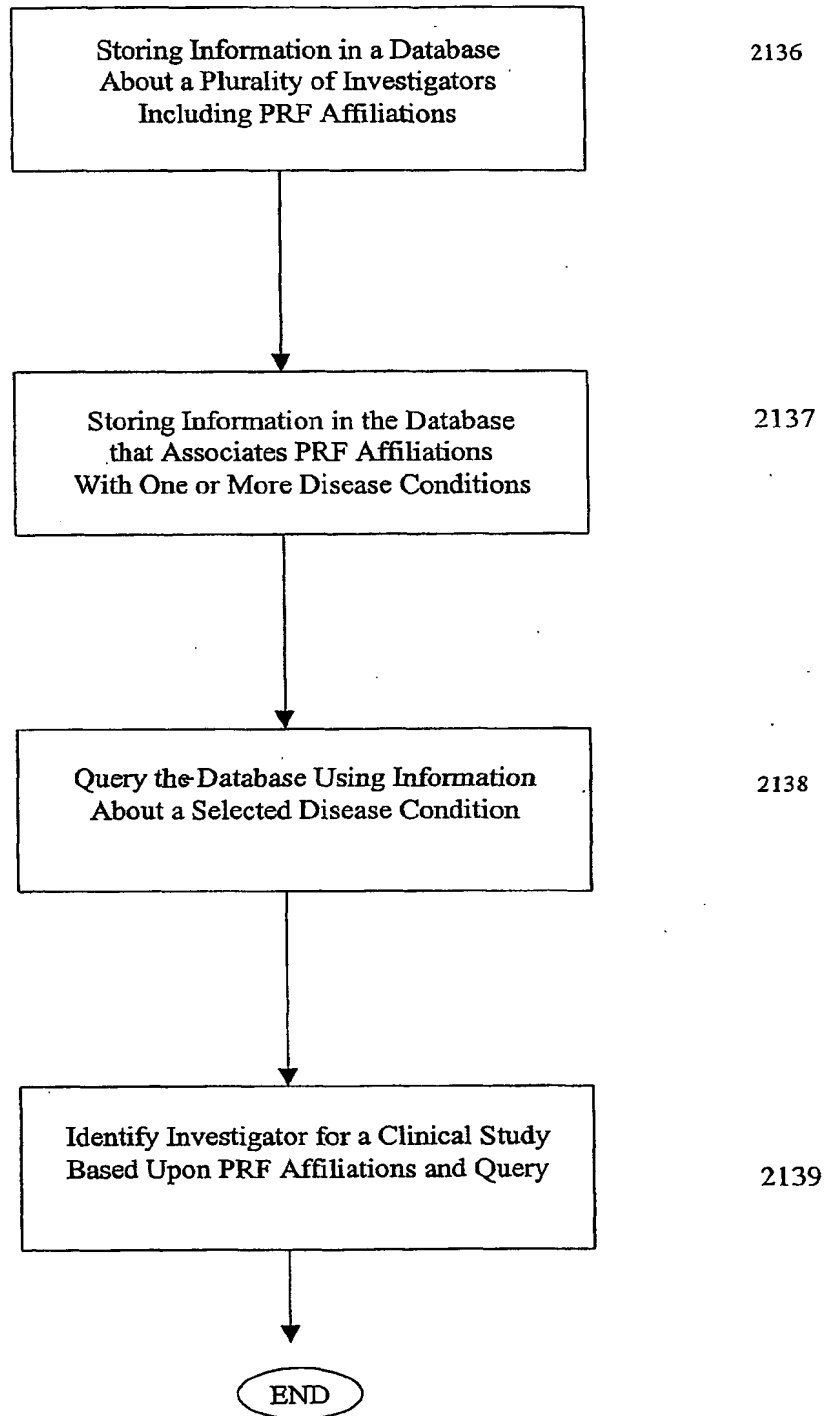


FIG. 21J

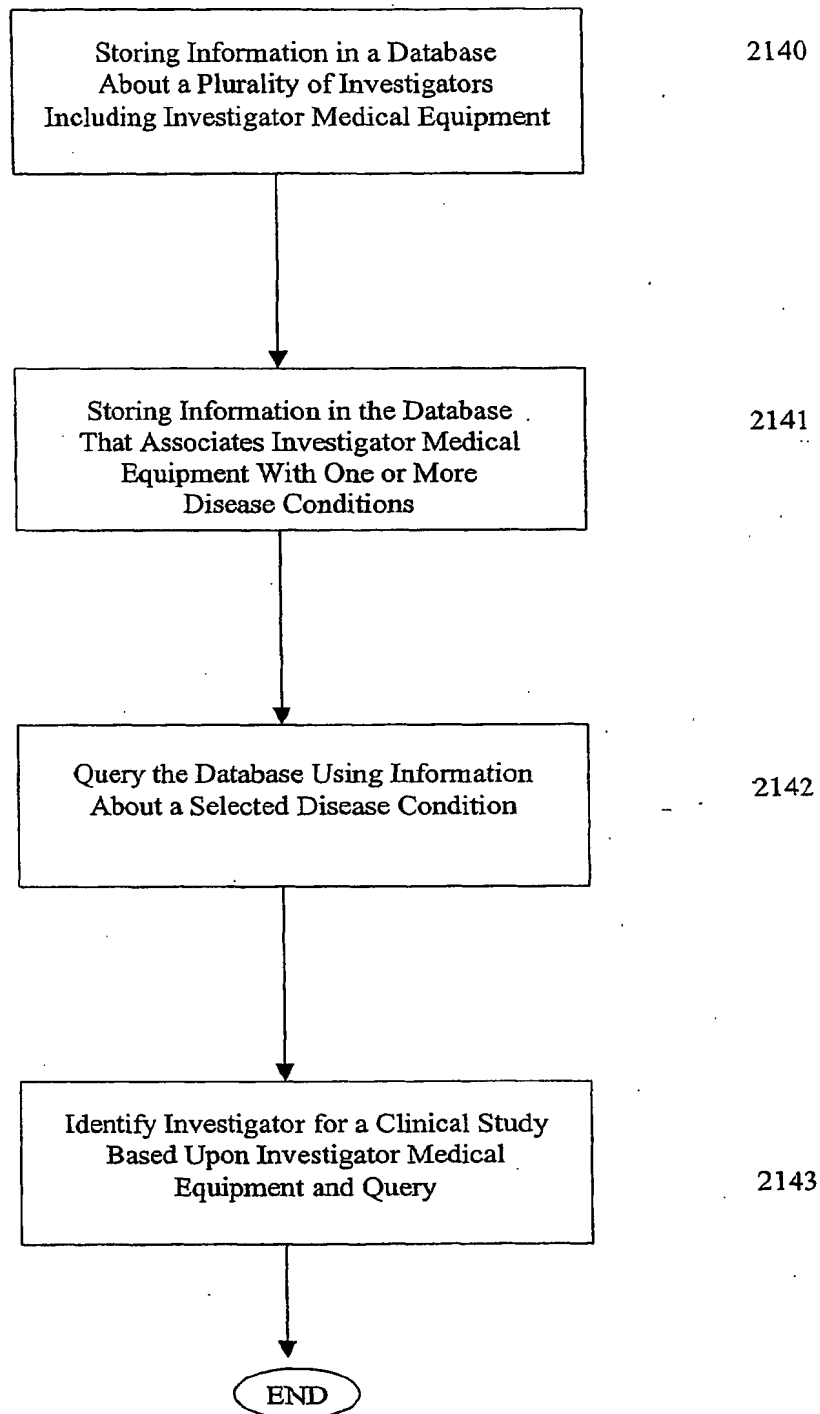


FIG. 21K

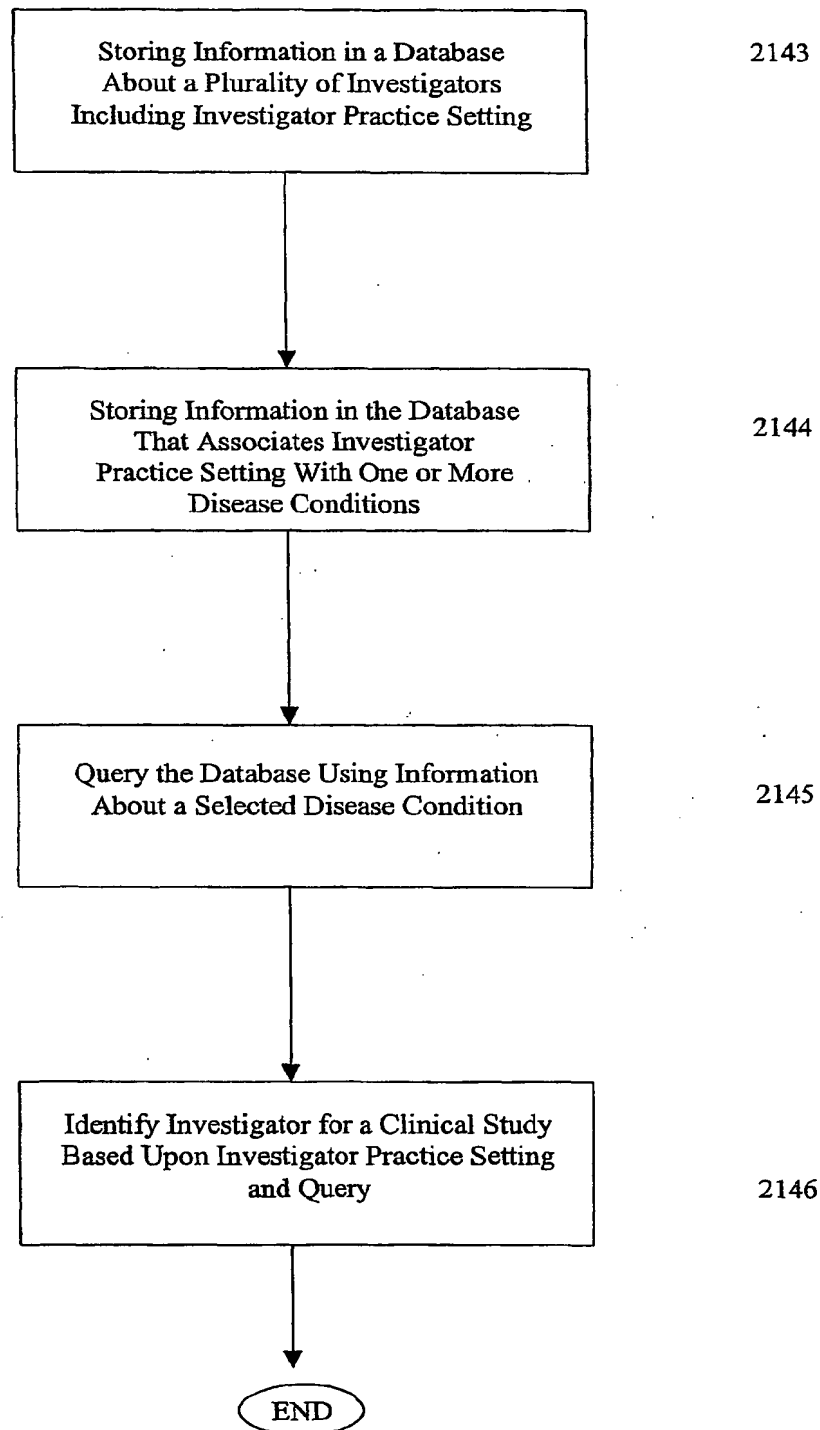


FIG. 21L

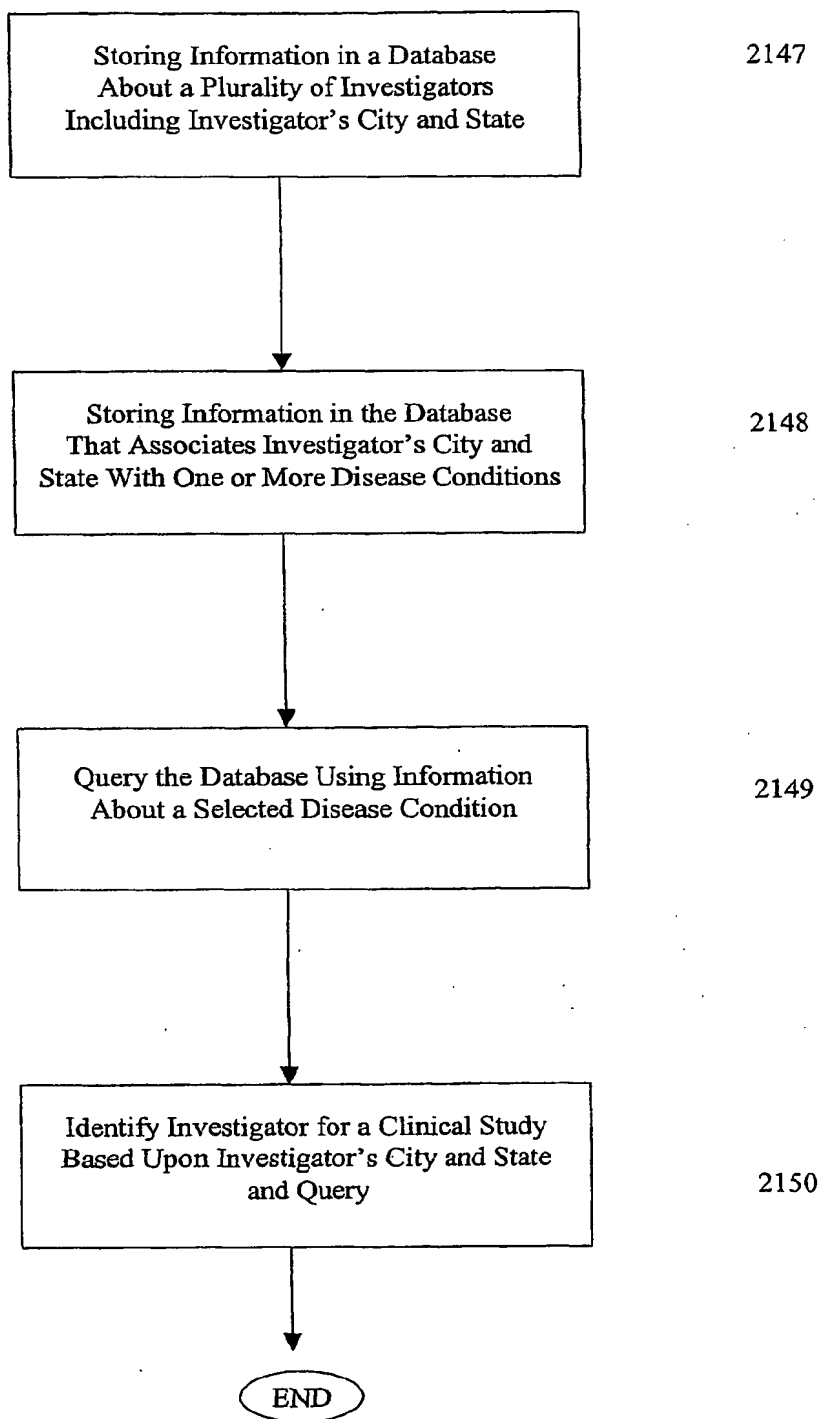


FIG. 21M

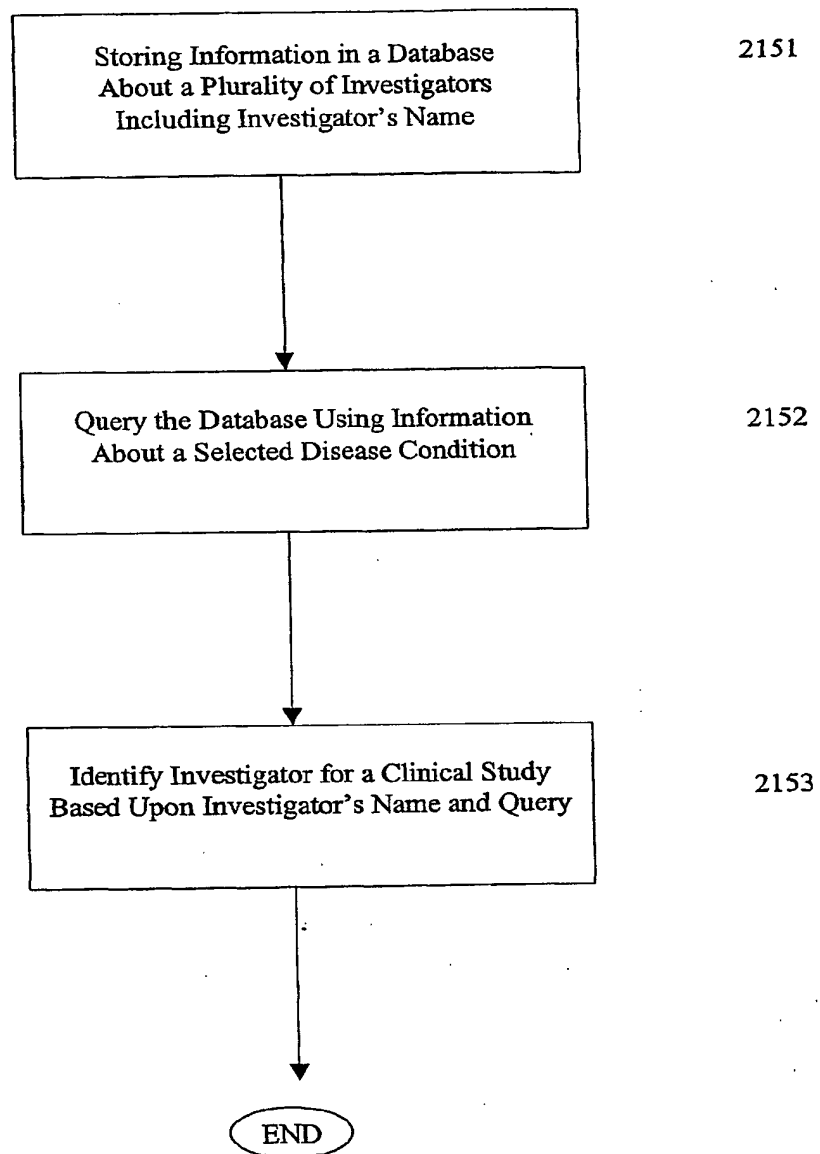


FIG. 21N



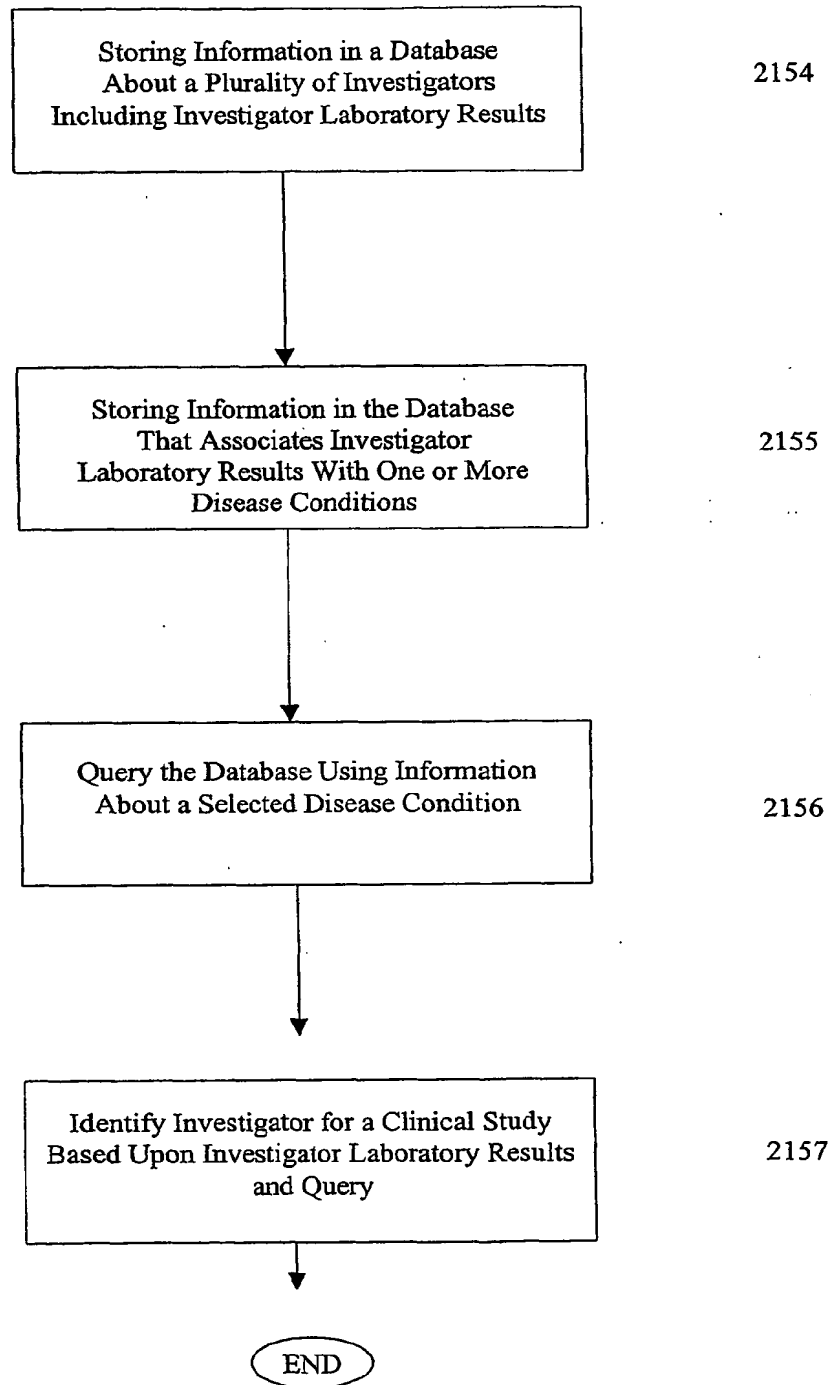


Fig. 210

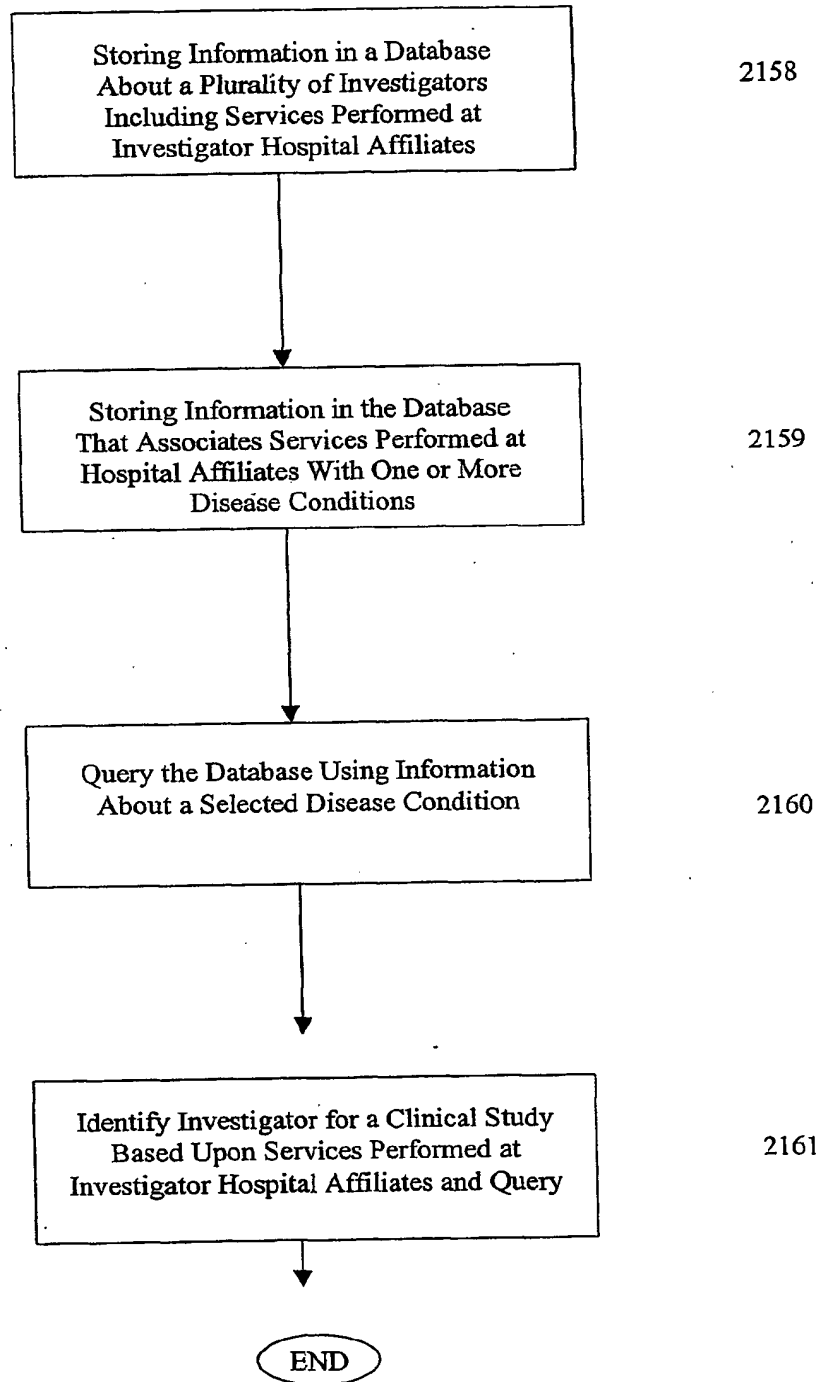


Fig. 21P

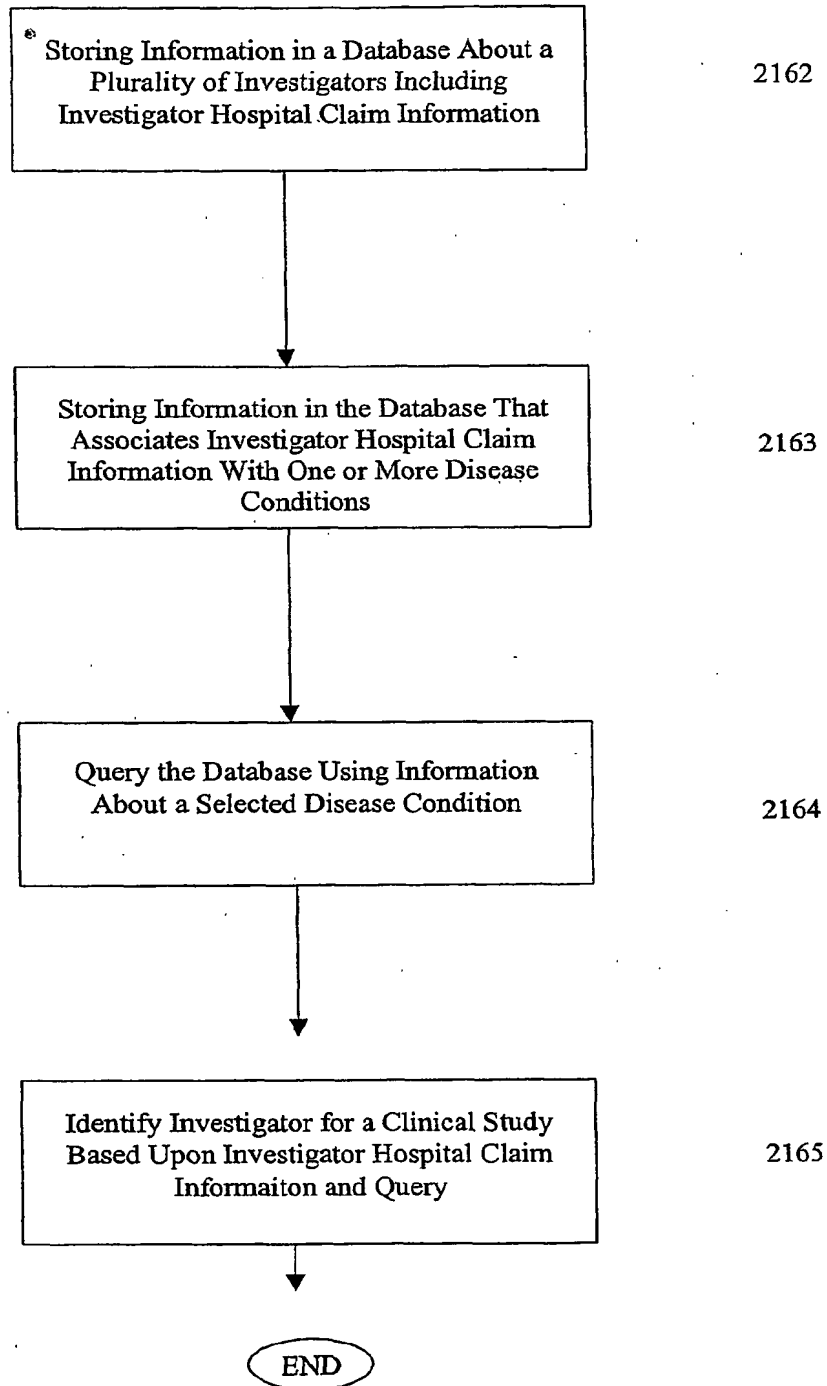


Fig. 21Q

STLDEV01 -- Display1 / Investigator

## INV STUDY PERFORMANCE

INVESTIGATOR\_ID: CHAR(18)  
STUDY\_PRF\_ID: CHAR(18)  
SOURCE\_CD: CHAR(18)  
SPONSOR\_ID: CHAR(18)  
SPONSOR\_CRO\_NAME: CHAR(18)  
PROTOCOL\_NUMBER: CHAR(18)  
STUDY\_PHASE\_CD: CHAR(18)  
DRUG\_NAME: CHAR(18)  
DRUG\_CLASS: CHAR(18)  
THERA\_CONDITION\_CD: CHAR(18)  
START\_DATE: CHAR(18)  
NUM\_ENROLLMENT\_COMMITMENT: CHAR(18)  
NUM\_PATIENTS\_ENROLLED: CHAR(18)  
ENROLLMENT\_MONTHS: CHAR(18)  
ENROLLMENT\_MET\_IND: CHAR(18)  
TIMEFRAME\_MET\_IND: CHAR(18)  
PLACEBO\_RESPONSE\_RATE: CHAR(18)  
NUM\_PATIENTS\_EVALUABLE: CHAR(18)  
MICROBIOLOGIC\_EVALUABLE: CHAR(18)  
BACTERIAL\_EVALUABLE: CHAR(18)  
NOTES: CHAR(18)  
CREATE\_DATE: CHAR(18)  
UPDATE\_DATE: CHAR(18)  
CREATE\_BY: CHAR(18)  
UPDATE\_BY: CHAR(18)

## INV SPECIALTY

INVESTIGATOR\_ID: NUMBER(8)  
SPECIALTY\_CD: VARCHAR2(6)  
SOURCE\_CD: VARCHAR2(12)  
BOARD\_COMPLETE\_CD: VARCHAR2(12)  
CREATE\_DATE: DATE  
UPDATE\_DATE: DATE  
CREATE\_BY: INTEGER  
UPDATE\_BY: INTEGER

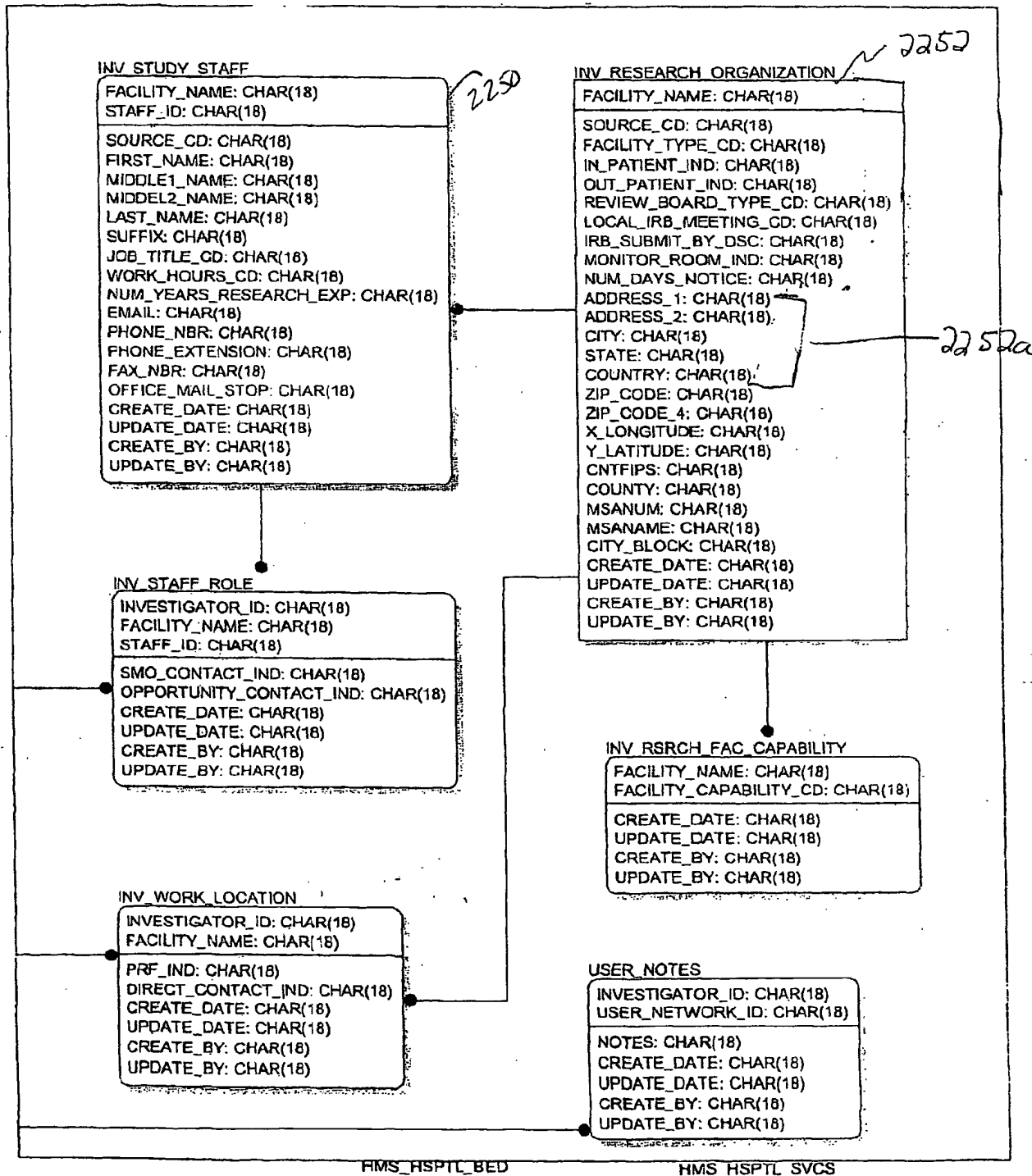
## INV PATIENT POPULATION

INVESTIGATOR\_ID: CHAR(18)  
INDICATION\_CD: CHAR(18)  
ANNUAL\_PATIENTS\_TREATED: CHAR(18)  
ANNUAL\_NEW\_PATIENTS\_TREATED: CHAR(18)  
INTERESTED\_IND: CHAR(18)  
CREATE\_BY: CHAR(18)  
UPDATE\_BY: CHAR(18)  
CREATE\_DATE: CHAR(18)  
UPDATE\_DATE: CHAR(18)

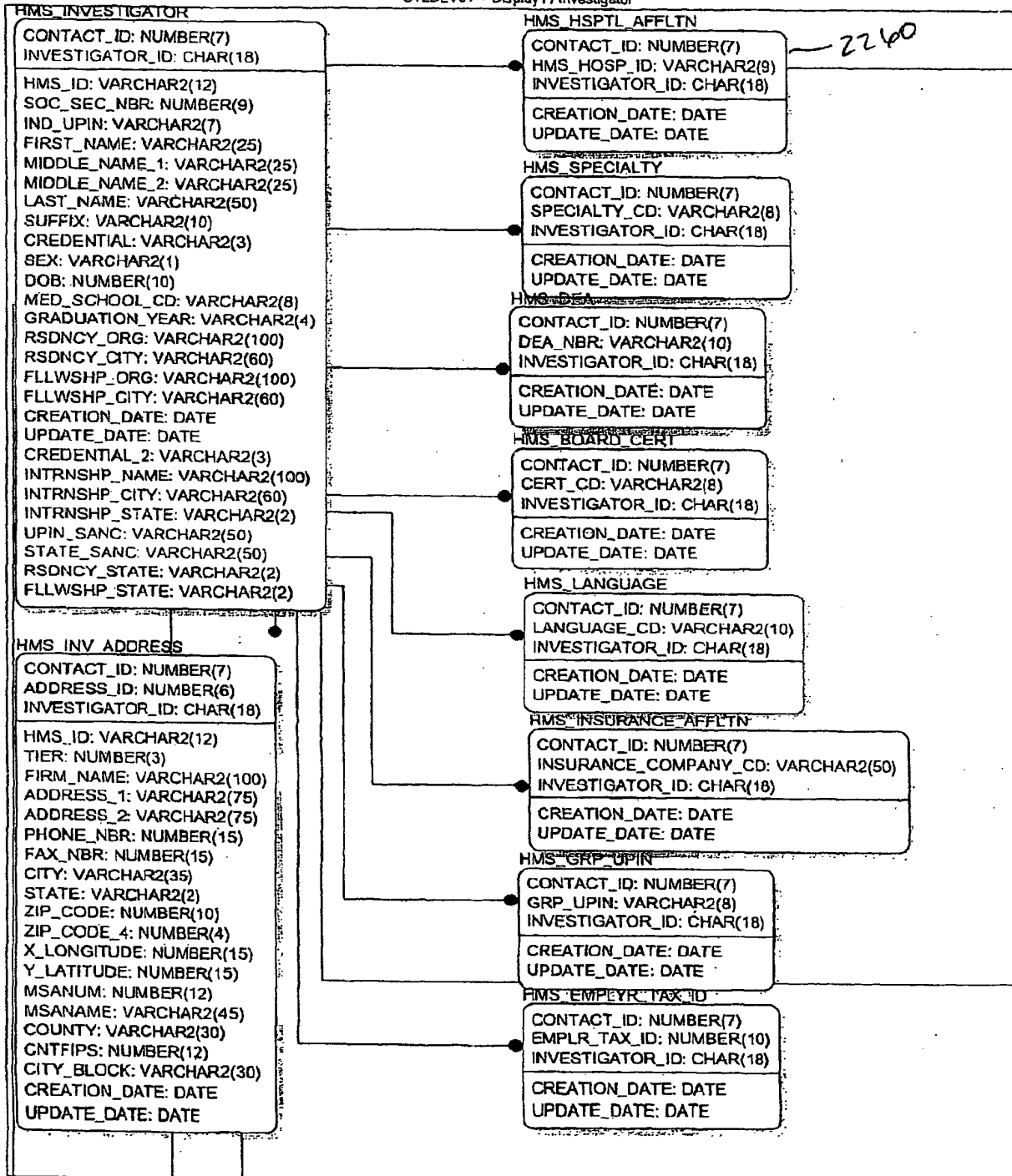
## INV INVESTIGATOR

INVESTIGATOR\_ID: CHAR(18)  
SOURCE\_CD: CHAR(18)  
HMS\_ID: CHAR(18)  
FIRST\_NAME: CHAR(18)  
MIDDLE1: CHAR(18)  
MIDDLE2: CHAR(18)  
LAST\_NAME: CHAR(18)  
SUFFIX: CHAR(18)  
COUNTRY: CHAR(18)  
SOC\_SEC\_NBR: CHAR(18)  
IND\_UPIN: CHAR(18)  
SEX: CHAR(18)  
DOB: CHAR(18)  
MED\_SCHOOL\_CD: CHAR(18)  
GRADUATION\_YEAR: CHAR(18)  
RSDNCY\_ORG: CHAR(18)  
RSDNCY\_CITY: CHAR(18)  
FLLWSHP\_ORG: CHAR(18)  
FLLWSHP\_CITY: CHAR(18)  
DEGREE1: CHAR(18)  
DEGREE2: CHAR(18)  
PHONE\_NBR: CHAR(18)  
PHONE\_EXTENSION: CHAR(18)  
FAX\_NBR: CHAR(18)  
EMAIL: CHAR(18)  
CREDENTIAL: CHAR(18)  
DELETE\_REASON\_CD: CHAR(18)  
DELETE\_REQUEST\_DATE: CHAR(18)  
WRONG\_NUMBER\_IND: CHAR(18)  
CV\_RECEIVED\_DATE: CHAR(18)  
QUESTIONNAIRE\_RETURNED\_DATE: CHAR(18)  
SMO\_RELATIONSHIP\_CD: CHAR(18)  
PRACTICE\_TYPE\_CD: CHAR(18)  
PRIMARY\_IN\_OUT\_CD: CHAR(18)  
CRO\_NUM\_DAYS\_NOTICE: CHAR(18)  
PHASE1\_EXPERIENCE\_IND: CHAR(18)  
PHASE2\_EXPERIENCE\_IND: CHAR(18)  
PHASE3\_EXPERIENCE\_IND: CHAR(18)  
PHASE4\_EXPERIENCE\_IND: CHAR(18)  
PATIENT\_DATABASE\_IND: CHAR(18)  
SOFTWARE\_PACKAGE\_NAME: CHAR(18)  
CREATE\_DATE: CHAR(18)  
UPDATE\_DATE: CHAR(18)  
CREATE\_BY: CHAR(18)  
UPDATE\_BY: CHAR(18)

HMS INVESTIGATOR



STLDEV01 -- Display1 / Investigator



22C

STLDEV01 - Display1 / Investigator

REPIAB\_SVCS: VARCHAR2(1)  
RESPIR\_SVCS: VARCHAR2(1)  
SELF CARE\_SVCS: VARCHAR2(1)  
SKNLT\_SVCS: VARCHAR2(1)  
SOC SVC\_SVCS: VARCHAR2(1)  
SPEECH\_SVCS: VARCHAR2(1)  
THERD\_SVCS: VARCHAR2(1)  
TRAUMA\_SVCS: VARCHAR2(1)  
XRADT\_SVCS: VARCHAR2(1)  
CREATION\_DATE: DATE  
UPDATE\_DATE: DATE

22D

STLDEV01 - Display 1 / Investigator

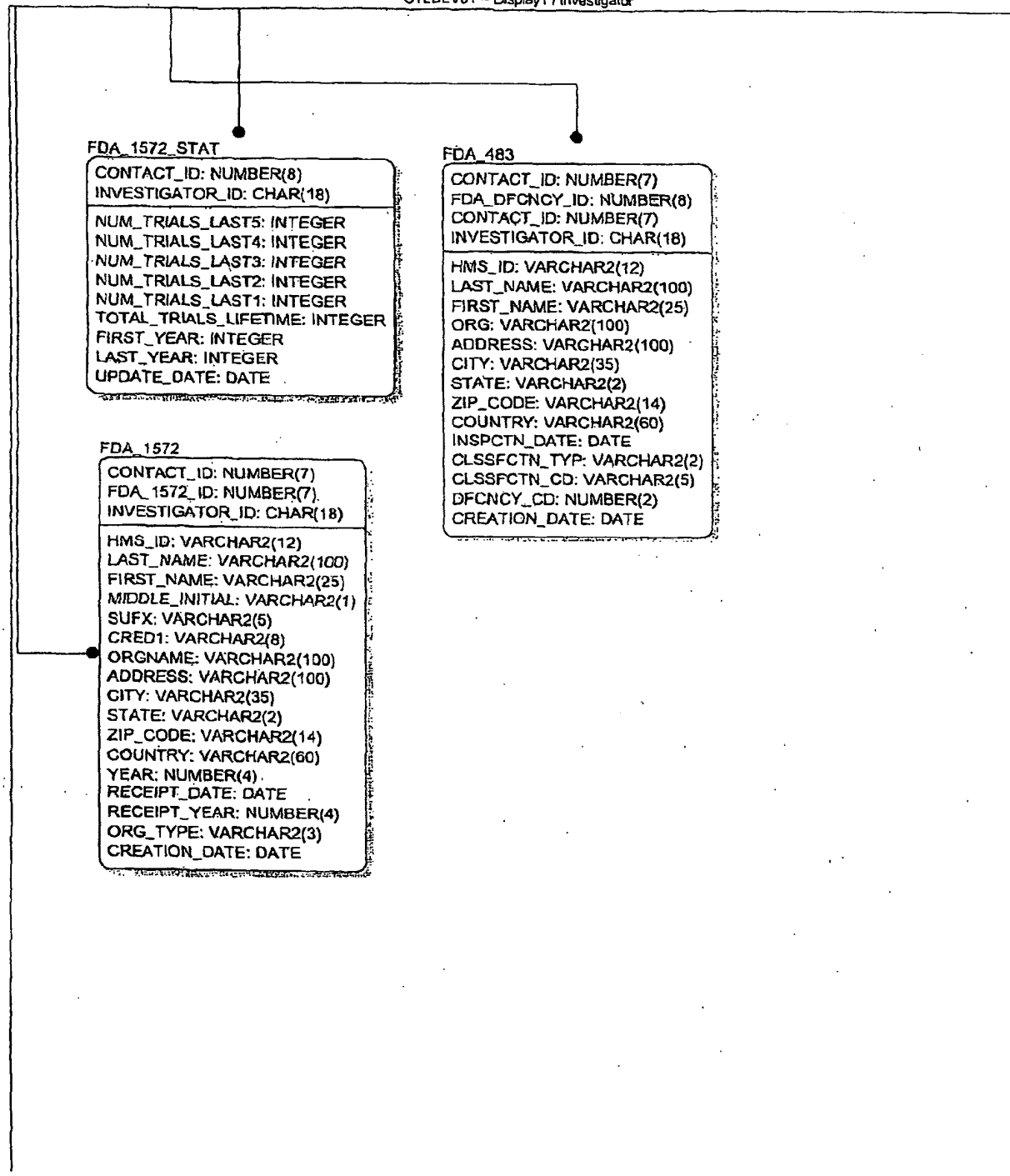
HMS_HSPTL	HMS_HSPTL_BED	HMS_HSPTL_SVCS
<b>CONTACT_ID:</b> NUMBER(7) <b>HMS_HOSP_ID:</b> VARCHAR2(9) <b>INVESTIGATOR_ID:</b> CHAR(18)  <b>HSPTL_NAME:</b> VARCHAR2(100) <b>DEPT_NAME:</b> VARCHAR2(50) <b>BRANCH_NAME:</b> VARCHAR2(50) <b>ADDRESS_1:</b> VARCHAR2(75) <b>ADDRESS_2:</b> VARCHAR2(75) <b>CITY:</b> VARCHAR2(25) <b>STATE:</b> VARCHAR2(2) <b>ZIP_CODE:</b> VARCHAR2(6) <b>ZIP_CODE_4:</b> VARCHAR2(4) <b>PHONE_NBR:</b> VARCHAR2(13) <b>CEO:</b> VARCHAR2(50) <b>FIPS5:</b> VARCHAR2(10) <b>COUNTY:</b> VARCHAR2(50) <b>MSANUM:</b> VARCHAR2(12) <b>MSANAME:</b> VARCHAR2(50) <b>CENSUS_ID:</b> VARCHAR2(20) <b>X_LONGITUDE:</b> VARCHAR2(15) <b>Y_LATITUDE:</b> VARCHAR2(15) <b>SRVC_CD:</b> VARCHAR2(5) <b>CTRL_CD:</b> VARCHAR2(5) <b>LOS_CD:</b> VARCHAR2(5) <b>UNV_HSPTL_IND:</b> VARCHAR2(1) <b>TCH_HSPTL_IND:</b> VARCHAR2(1) <b>TEACHHOSP_IND:</b> VARCHAR2(1) <b>RESIDENCY_IND:</b> VARCHAR2(1) <b>MED_SCHL_IND:</b> VARCHAR2(1) <b>ALLIED_SCHL_IND:</b> VARCHAR2(1) <b>JCAHO_IND:</b> VARCHAR2(1) <b>MEDICARE_IND:</b> VARCHAR2(1) <b>CANCERCTR_IND:</b> VARCHAR2(1) <b>CLOSED_IND:</b> VARCHAR2(1) <b>CREATION_DATE:</b> DATE <b>UPDATE_DATE:</b> DATE	<b>CONTACT_ID:</b> NUMBER(7) <b>HMS_HOSP_ID:</b> VARCHAR2(9) <b>INVESTIGATOR_ID:</b> CHAR(18)  <b>HMS_STF_BEDS:</b> NUMBER(9) <b>HMS_HSP_BEDS:</b> NUMBER(9) <b>HMS_TOT_BEDS:</b> NUMBER(9) <b>HMS_STRM_BEDS:</b> NUMBER(9) <b>HMS_LTERM_BEDS:</b> NUMBER(9) <b>HMS_MDSRG_BEDS:</b> NUMBER(9) <b>HMS_ICU_BEDS:</b> NUMBER(9) <b>BEDS_OK:</b> VARCHAR2(5) <b>ICU_BEDS:</b> NUMBER(9) <b>CCU_BEDS:</b> NUMBER(9) <b>SICU_BEDS:</b> NUMBER(9) <b>NICU_BEDS:</b> NUMBER(9) <b>NINT_BEDS:</b> NUMBER(9) <b>PICU_BEDS:</b> NUMBER(9) <b>PEDI_BEDS:</b> NUMBER(9) <b>OBNB_BEDS:</b> NUMBER(9) <b>PSYC_BEDS:</b> NUMBER(9) <b>BURN_BEDS:</b> NUMBER(9) <b>ALCH_BEDS:</b> NUMBER(9) <b>REHB_BEDS:</b> NUMBER(9) <b>OTHR_BEDS:</b> NUMBER(9) <b>CREATION_DATE:</b> DATE <b>UPDATE_DATE:</b> DATE	<b>CONTACT_ID:</b> NUMBER(7) <b>HMS_HOSP_ID:</b> VARCHAR2(9) <b>INVESTIGATOR_ID:</b> CHAR(18)  <b>AIDS_SVCS:</b> VARCHAR2(1) <b>ANSTH_SVCS:</b> VARCHAR2(1) <b>ANGPLSTY_SVCS:</b> VARCHAR2(1) <b>BLOODBNK_SVCS:</b> VARCHAR2(1) <b>BMTRNSPL_SVCS:</b> VARCHAR2(1) <b>BURNCTR_SVCS:</b> VARCHAR2(1) <b>CRDCTH_SVCS:</b> VARCHAR2(1) <b>CVSRGY_SVCS:</b> VARCHAR2(1) <b>CHIRO_SVCS:</b> VARCHAR2(1) <b>CLPSY_SVCS:</b> VARCHAR2(1) <b>CT_SVCS:</b> VARCHAR2(1) <b>DENTL_SVCS:</b> VARCHAR2(1) <b>ULTRNSD_SVCS:</b> VARCHAR2(1) <b>DIETRTY_SVCS:</b> VARCHAR2(1) <b>ECARD_SVCS:</b> VARCHAR2(1) <b>ECONV_SVCS:</b> VARCHAR2(1) <b>EMRGCY_SVCS:</b> VARCHAR2(1) <b>ESWL_SVCS:</b> VARCHAR2(1) <b>LABAN_SVCS:</b> VARCHAR2(1) <b>HEART_SVCS:</b> VARCHAR2(1) <b>HRTLUNG_SVCS:</b> VARCHAR2(1) <b>HEMODIAL_SVCS:</b> VARCHAR2(1) <b>HOMCRE_SVCS:</b> VARCHAR2(1) <b>HOSPCE_SVCS:</b> VARCHAR2(1) <b>CCU_SVCS:</b> VARCHAR2(1) <b>ICU_SVCS:</b> VARCHAR2(1) <b>KIDNEY_SVCS:</b> VARCHAR2(1) <b>LABCLNC_SVCS:</b> VARCHAR2(1) <b>LIVER_SVCS:</b> VARCHAR2(1) <b>LUNG_SVCS:</b> VARCHAR2(1) <b>MEGVRAD_SVCS:</b> VARCHAR2(1) <b>NEONUNT_SVCS:</b> VARCHAR2(1) <b>NICU_SVCS:</b> VARCHAR2(1) <b>MRI_SVCS:</b> VARCHAR2(1) <b>NEURO_SVCS:</b> VARCHAR2(1) <b>NSURG_SVCS:</b> VARCHAR2(1) <b>NUCMED_SVCS:</b> VARCHAR2(1) <b>OBSRVA_SVCS:</b> VARCHAR2(1) <b>OBSTE_SVCS:</b> VARCHAR2(1) <b>OCCTH_SVCS:</b> VARCHAR2(1) <b>OPNHT_SVCS:</b> VARCHAR2(1) <b>OPTOM_SVCS:</b> VARCHAR2(1) <b>ORGBANK_SVCS:</b> VARCHAR2(1) <b>ORGAN_SVCS:</b> VARCHAR2(1) <b>OUTPAT_SVCS:</b> VARCHAR2(1) <b>OUTSRG_SVCS:</b> VARCHAR2(1) <b>PANCR_SVCS:</b> VARCHAR2(1) <b>PEDIAT_SVCS:</b> VARCHAR2(1) <b>PHARM_SVCS:</b> VARCHAR2(1) <b>PHYTH_SVCS:</b> VARCHAR2(1) <b>PSTOP_SVCS:</b> VARCHAR2(1) <b>PSYED_SVCS:</b> VARCHAR2(1) <b>PULMON_SVCS:</b> VARCHAR2(1) <b>RADIM_SVCS:</b> VARCHAR2(1) <b>RECTH_SVCS:</b> VARCHAR2(1)

HMS_LICENSE
<b>CONTACT_ID:</b> NUMBER(7) <b>LICENSE_STATE_CD:</b> VARCHAR2(2) <b>INVESTIGATOR_ID:</b> CHAR(18)  <b>LICENSE_YEAR:</b> NUMBER(4) <b>CREATION_DATE:</b> DATE <b>UPDATE_DATE:</b> DATE

22E



STLDEV01 -- Display 1 / Investigator



22F

# Step 1 Disease Incidence Search

## Study - Angina

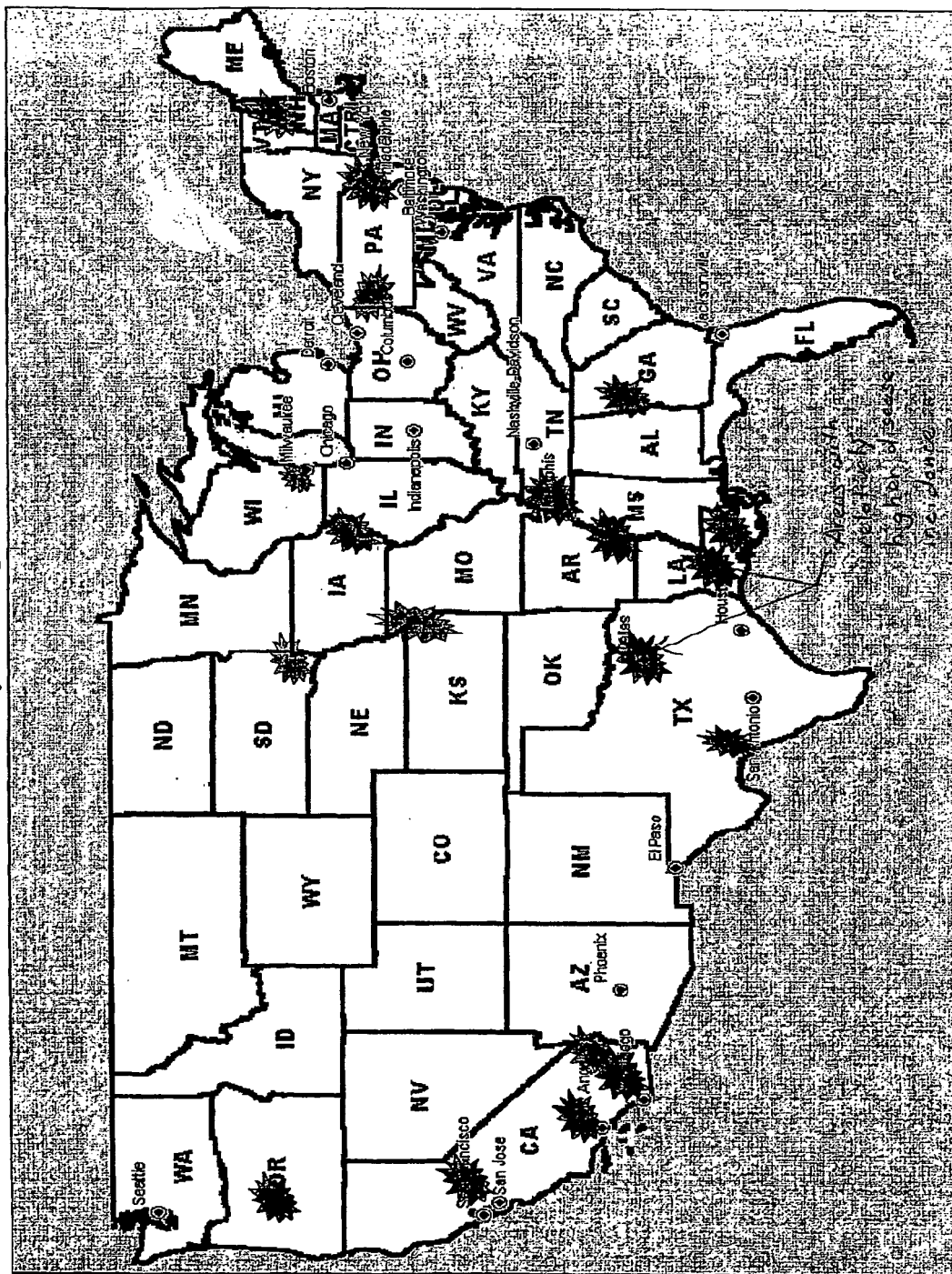


Fig. 226

7/8/89  
**Step 1 Dallas - Fort Worth Area**  
**Study - Angina**  
*Eligible Investigation Sites*

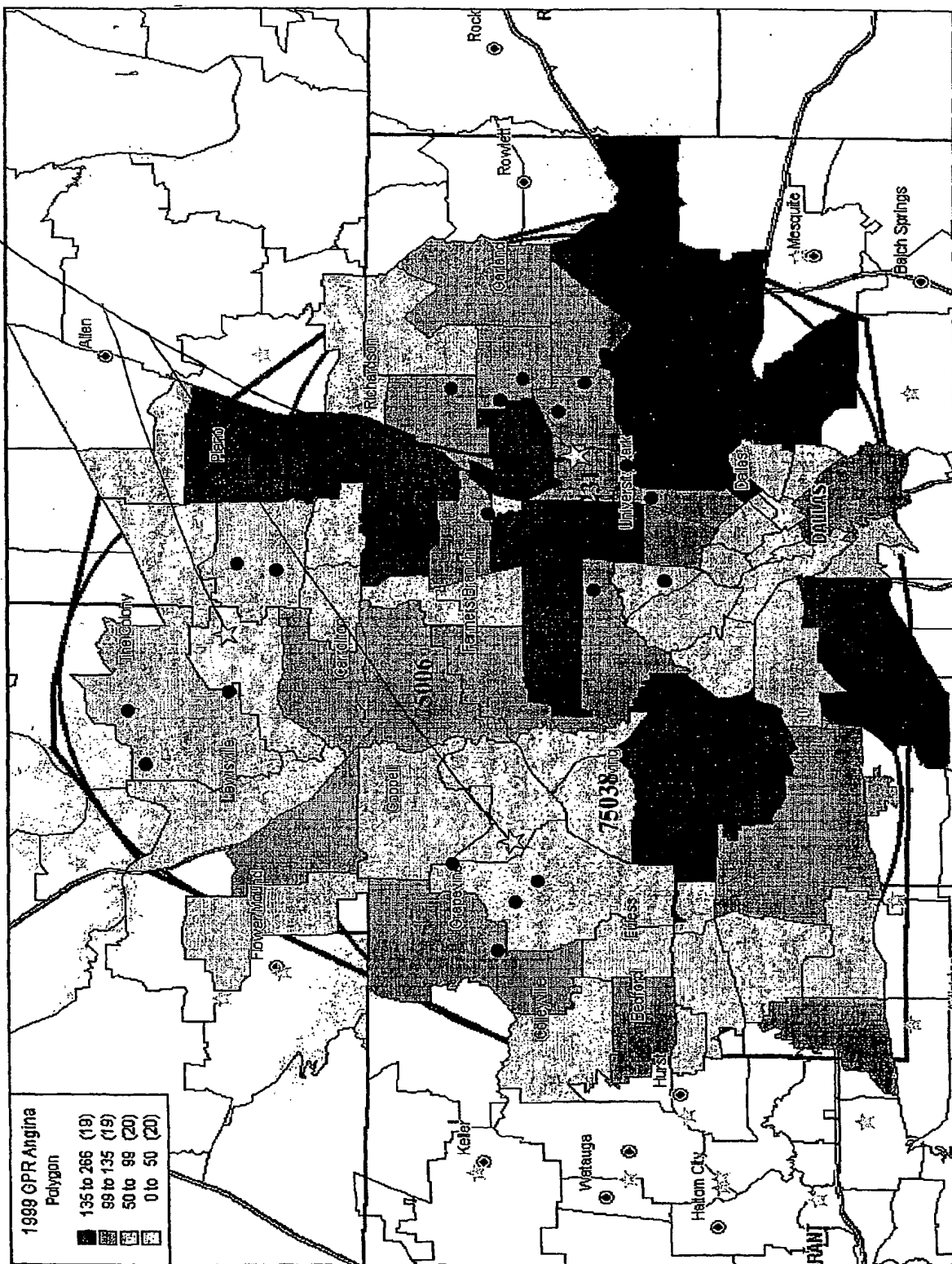


Fig. 224

# Step 2 Investigator Recruitment / Screening Case Study – Angina

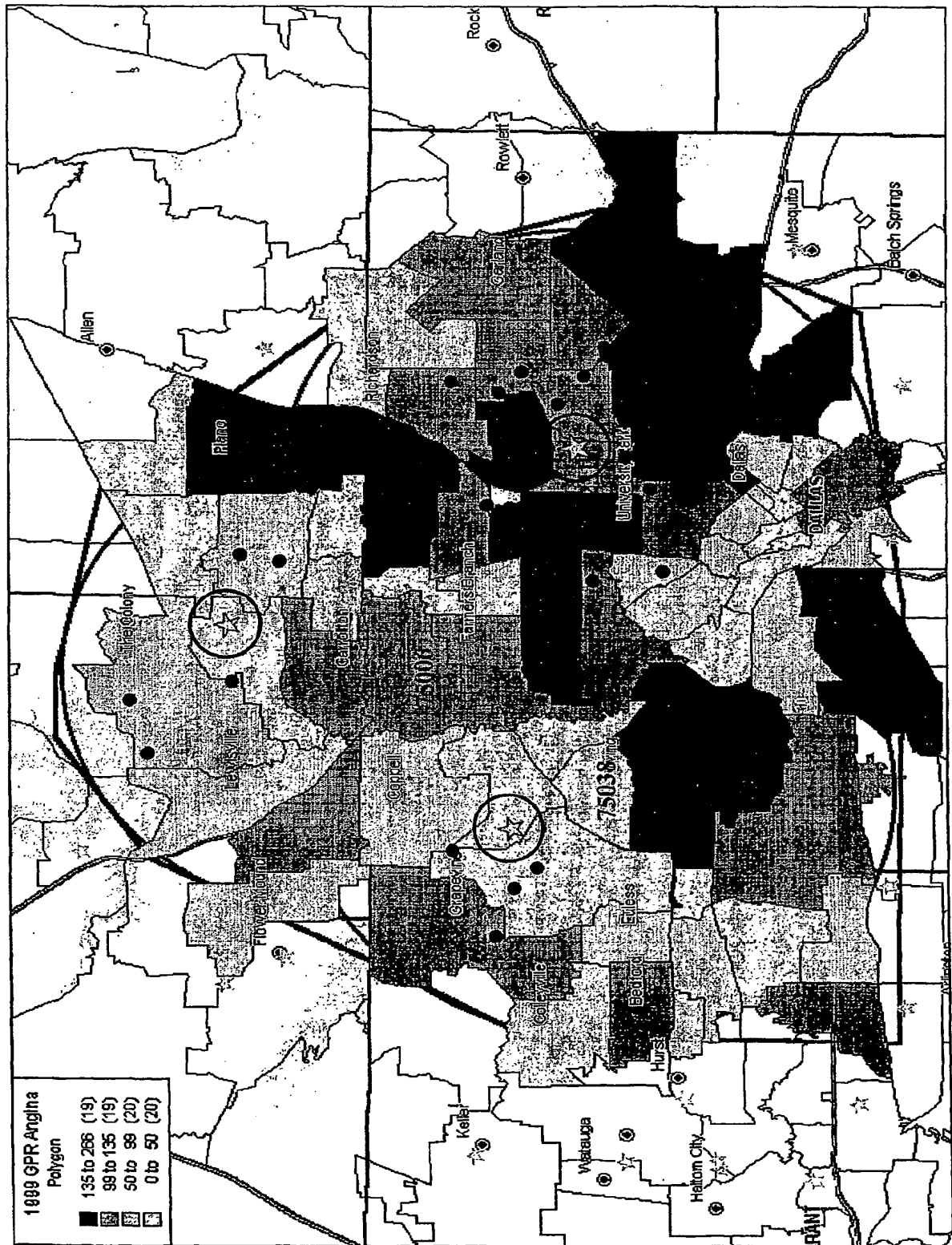


Fig. 2aI

## Case Study – Angina

## Step 3 Investigator Selection

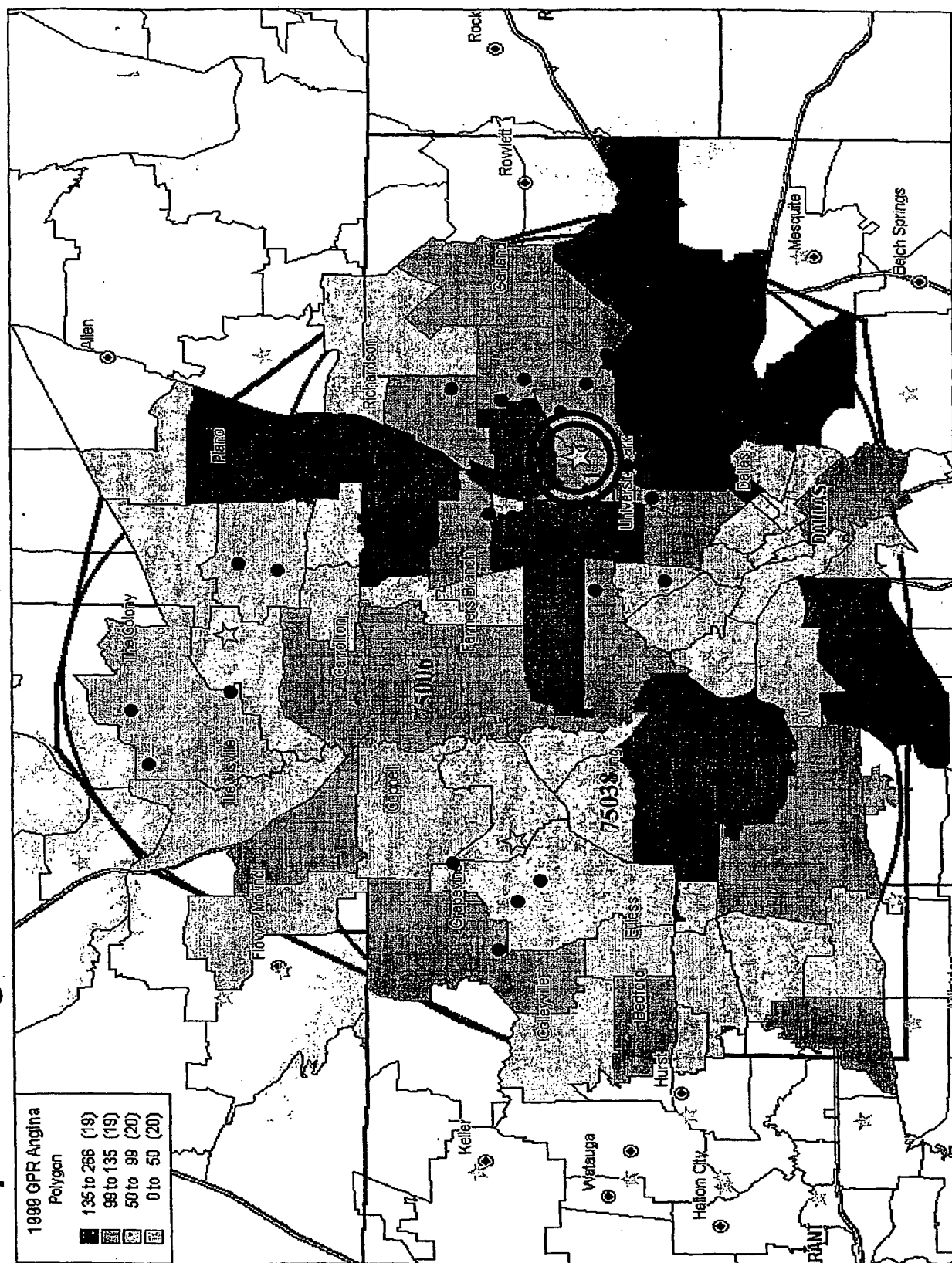
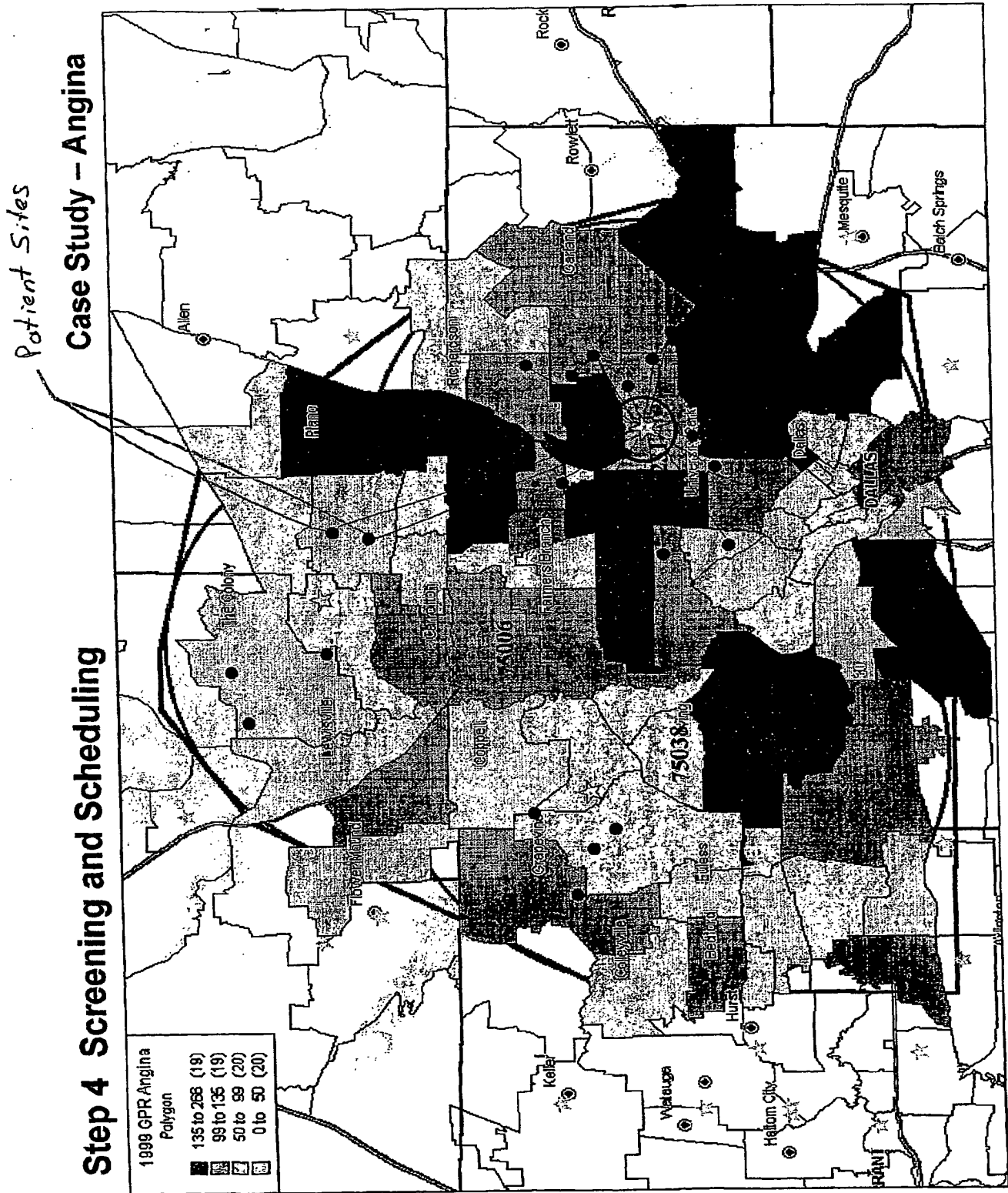


Fig. 225



Smith, John  
Specialty Cardiovascular Disease  
Internal Medicine



Contact Information Primary Research Facility Study Staff Trial Experience Provider Hospital Prismatic View

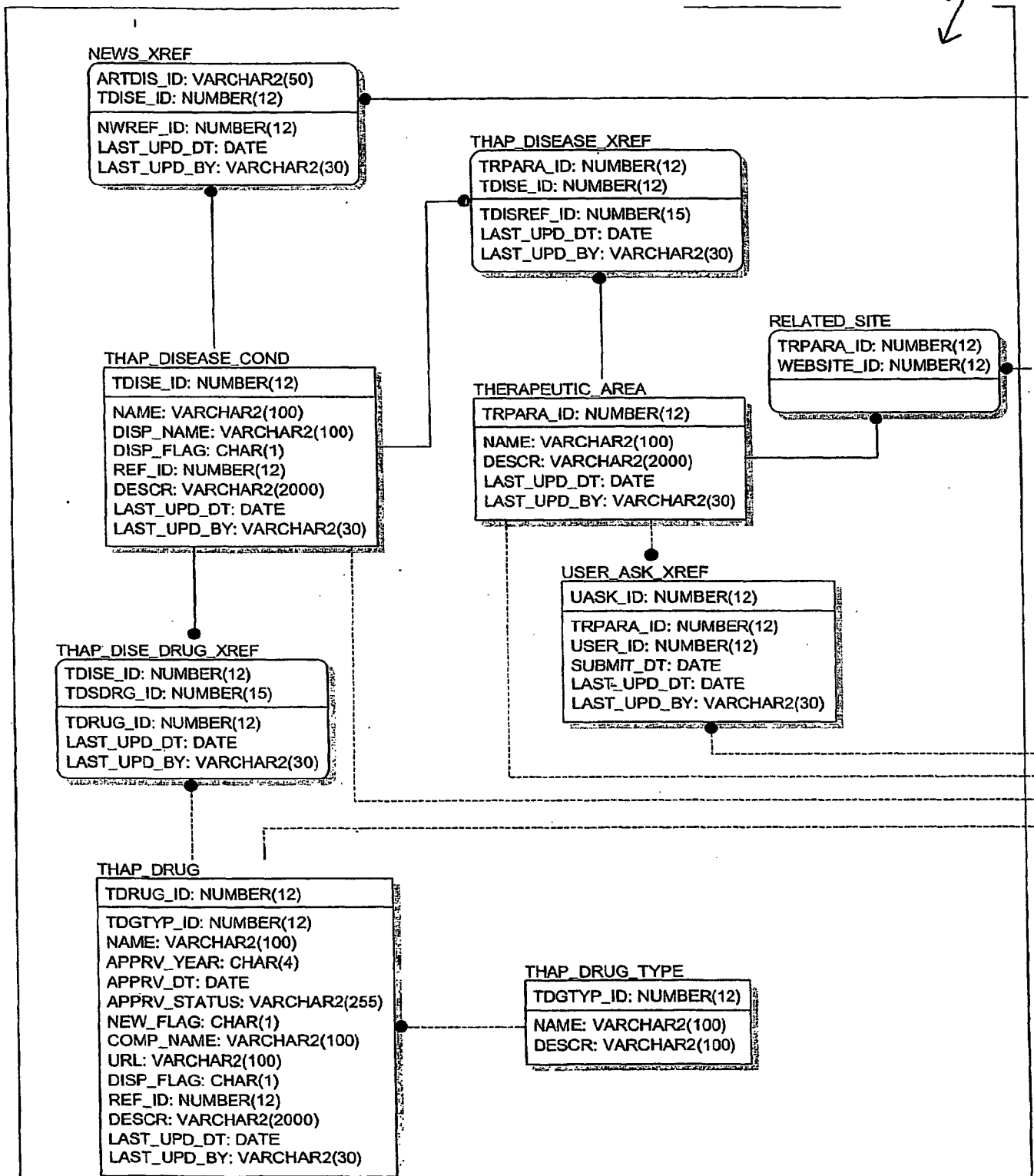
Yellow = ABC Pharma Trial

Indication	Start Date	Enrollment Commitment	Evaluable Patients	Timeframe (months)	Enrollment Percentage	ABC Pharma Rank
APT	1/15/2001	12	8	12	70%	4
CHF	11/1/2000	10	9	9	90%	
CHF	10/5/2000	10	9	9	90%	
CHD	7/1/2000	8	3	6	40%	2
CAD	6/1/1999	15	12	6	80%	
CHT	2/5/1999	8	7	10	90%	4
CHF	3/1/1998	10	8	12	80%	3
CHD	3/22/1997	6	4	10	60%	
CHD	6/1/1996	8	6	10	80%	

Aggregated data  
(2302)

Data supplied by  
sponsor  
viewing  
screen  
(2304)

Fig. 23

Fig.  
24A



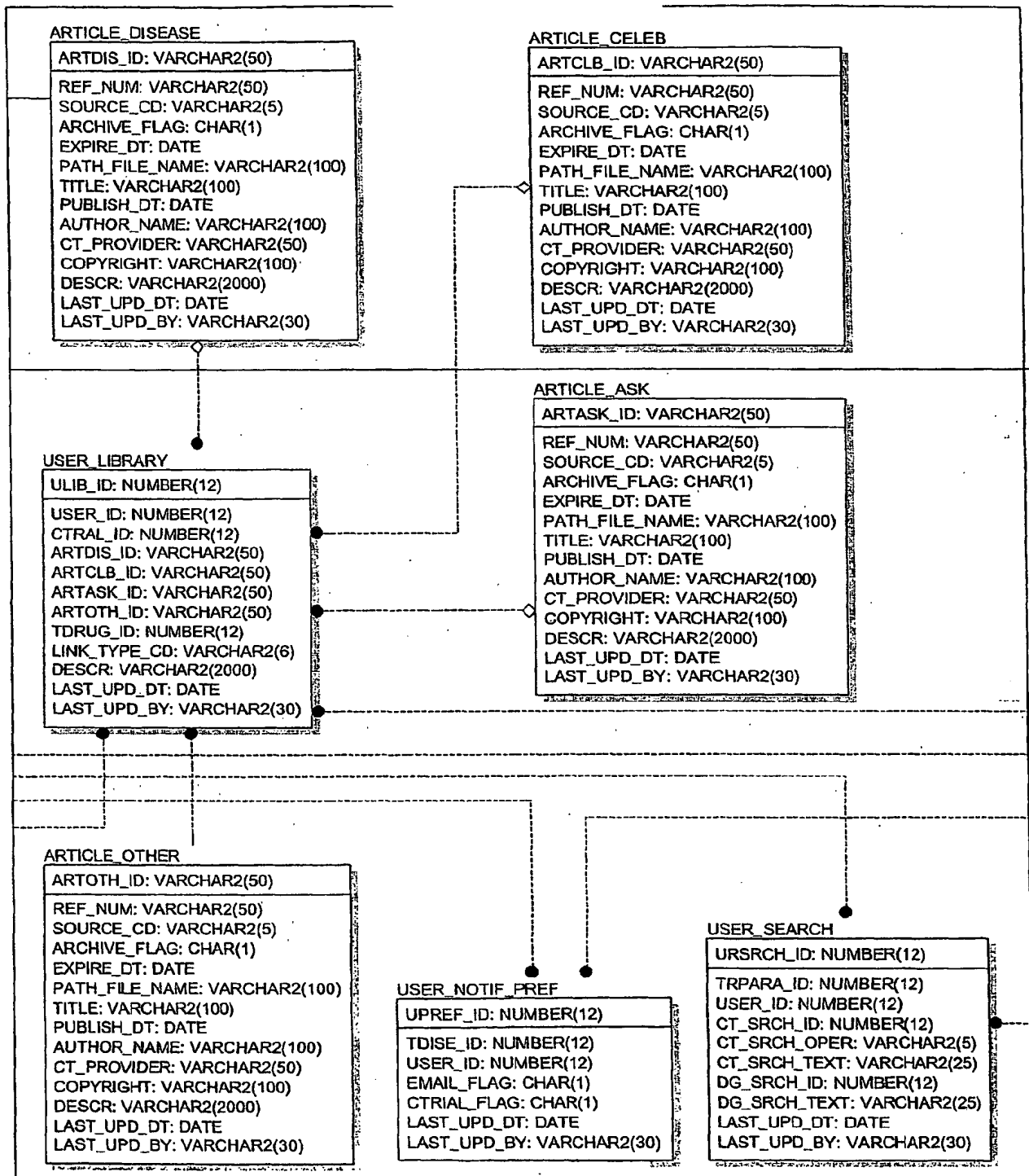


Fig. 24B

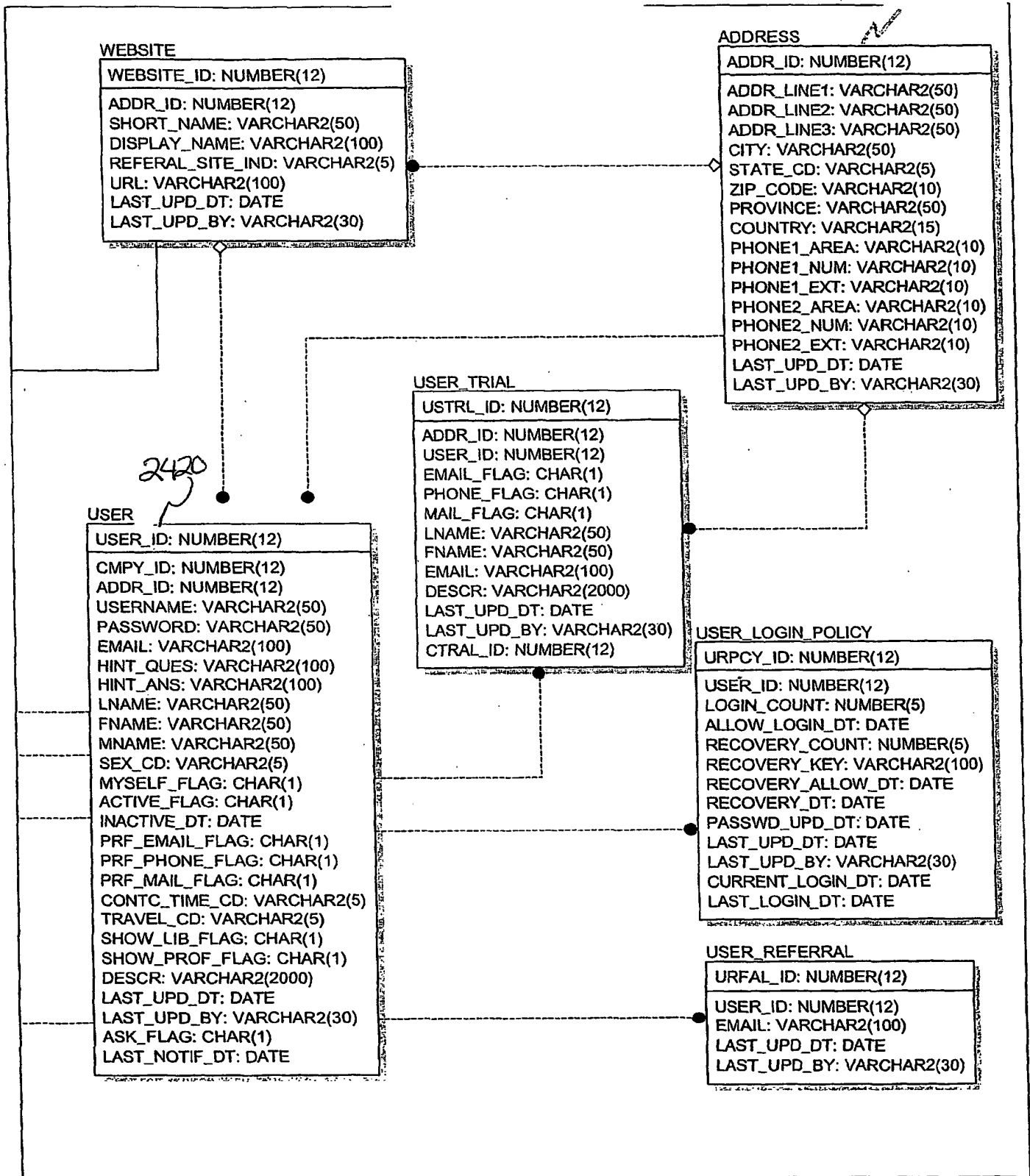


Fig 24C

## ACURIAN\_CONTENT\_TYPE

CONTYP_ID: NUMBER(12)
NAME: VARCHAR2(100)
DESCR: VARCHAR2(100)

## ACURIAN\_NOTIFICATION

NOTIF_ID: NUMBER(12)
NOTIF_TYPE: VARCHAR2(100)
NOTIF_DESC: VARCHAR2(100)
LAST_NOTIF_DT: DATE

## ACURIAN\_PUBLISH

PUBLISH_ID: NUMBER(12)
CONTYP_ID: NUMBER(12)
PUBLISH_DATE: DATE
TRPARA_ID: NUMBER(12)

Fig. 24D

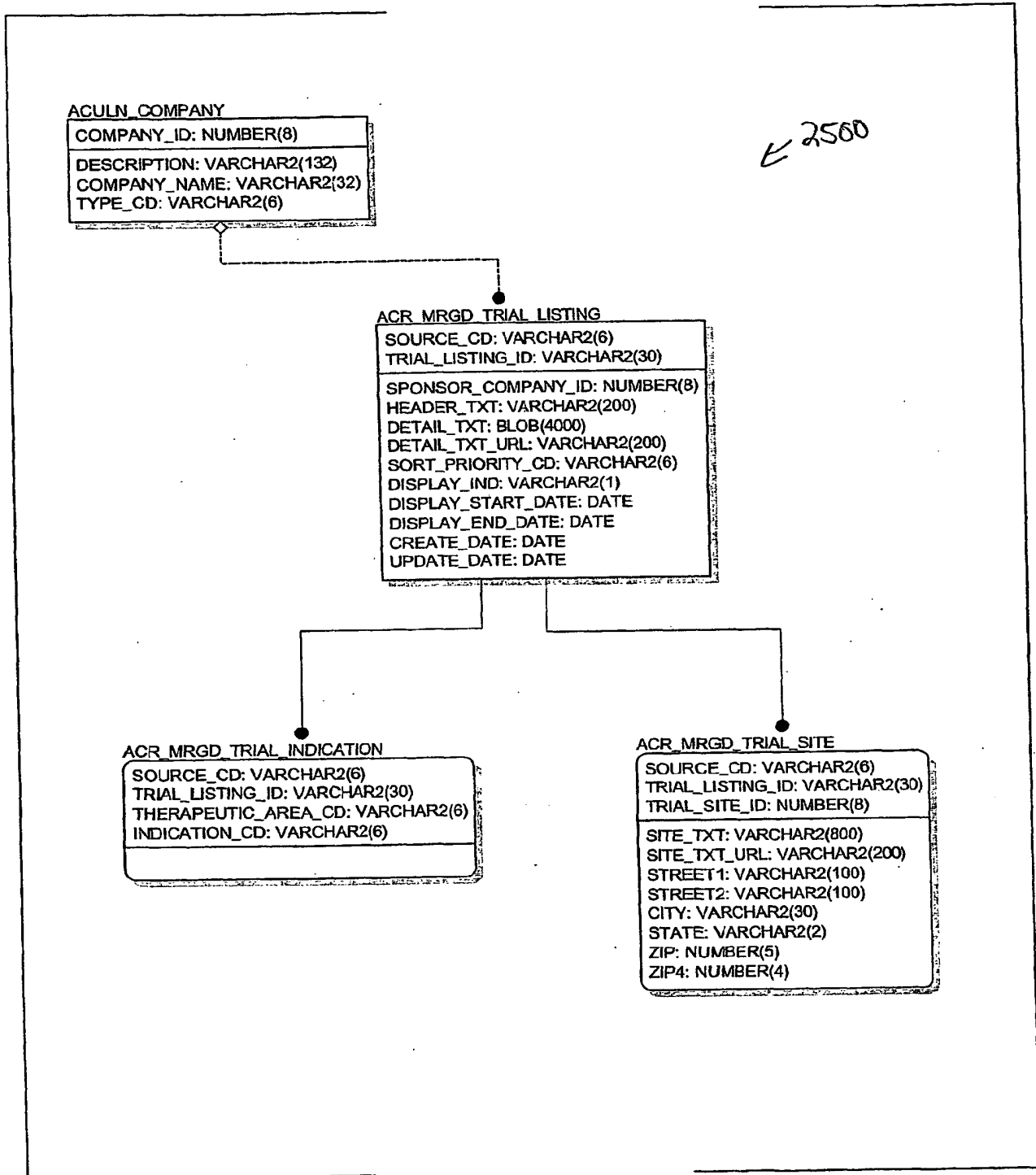
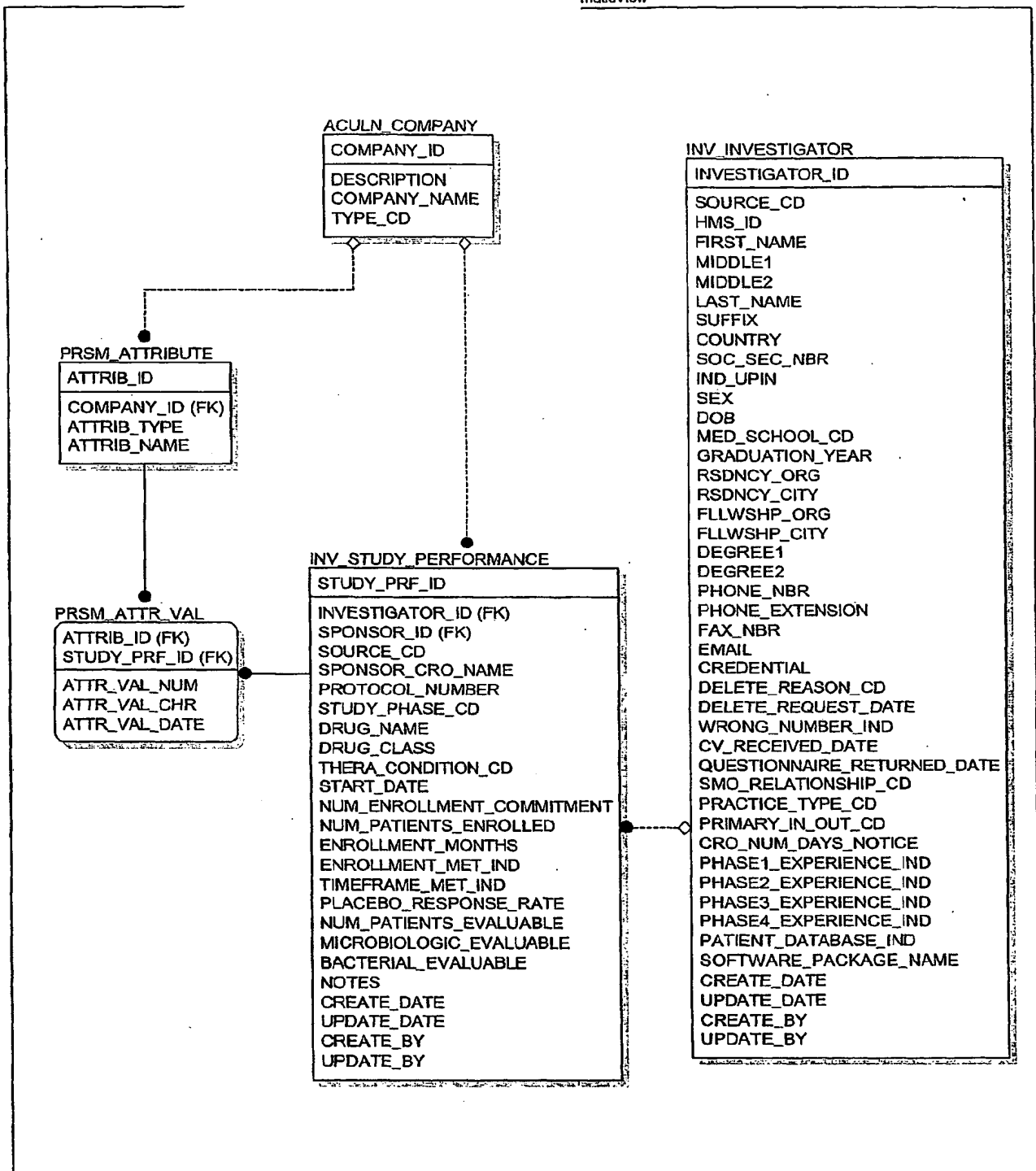


Fig. 25

maticView



1, 1 / 1, 1 - 9:45:14 AM, 1/29/01

Fig. 26

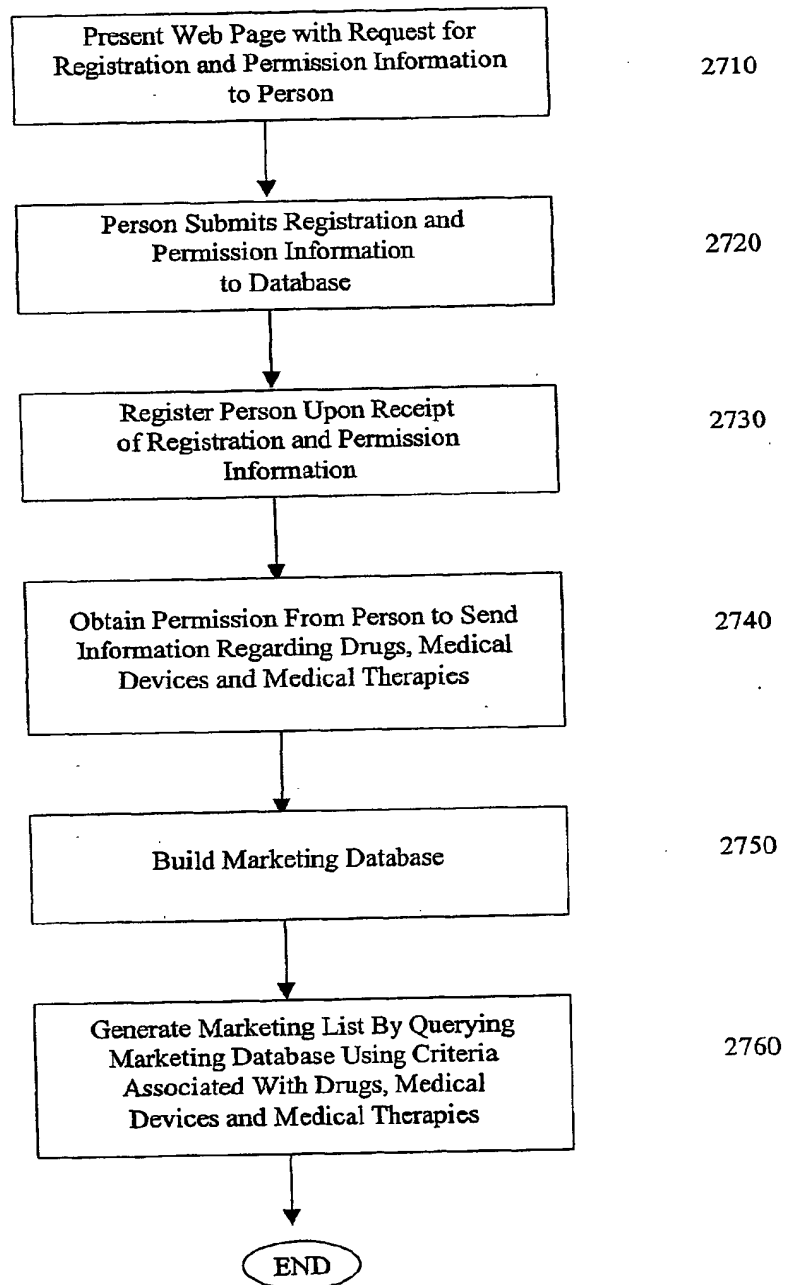


FIG. 27

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US01/02936

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :G06F 17/60

US CL :705/3

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 705/3, 2; 600/300

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST search (US Patents, EPO, JPO, Derwent), DIALOG search (business and marketing databases), PROQUEST search (all databases), see attached.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- A	US 5,991,731 A (COLON et al.) 23 November 1999, col. 1, lines 48-51, col. 4, lines 49-53, col. 6, lines 22-30 and col. 7, lines 46-54).	1, 16, and 26 ----- 2-15, 17-25, and 27-120
A	US 5,734,883 A (UMEN et al) 31 MArch 1998, see abstract)	1-120
A	ANONYMOUS. Public CROs: Clinikor Inc. R&D Directions. September 1999. Vol. 5 .No. 8. pp. 91.	1-120

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

10 MARCH 2001

Date of mailing of the international search report

24 APR 2001

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

TARIQ HAFIZ

Telephone No. (703) 305-9643

Form PCT/ISA/210 (second sheet) (July 1998)\*

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US01/02936

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	ANONYMOUS. Dialog file 16 (Gale group PROMT(R)). No. 6439375. drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patients on the Internet. PR Newswire. 3 pages.	1-120
A	ZOELLER, JANICE. Surfing for complementary info. American Druggist. September 1999. Vol. 216. No. 9. pp. 15.	1-120
A	MCCRAY, ALEXA T. A national resource for information on clinical trials. National Forum. September 1999. Vol. 79. No. 3. pp. 19-21.	1-120
A	UKENS, CAROL. CenterWatch is hub of clinical trials Web sites. Drug Topics. 19 April 1999. Vol. 143. No. 8. pp. 112.	1-120



CORRECTED VERSION

(19) World Intellectual Property Organization  
International Bureau(43) International Publication Date  
2 August 2001 (02.08.2001)

PCT

(10) International Publication Number  
WO 01/055942 A1(51) International Patent Classification<sup>7</sup>: G06F 17/60

(21) International Application Number: PCT/US01/02936

(22) International Filing Date: 29 January 2001 (29.01.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/178,634 28 January 2000 (28.01.2000) US

(71) Applicant (for all designated States except US): ACURIAN, INC. [US/US]; 2 Walnut Grove Drive, Suite 375, Horsham, PA 19044 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): TUCKER, Jennifer, L. [US/US]; 257 Windsor Way, Doylestown, PA 19044 (US). HOLLWAY, John, F. [US/US]; 19 Harrison Drive, Newtown Square, PA 19073 (US). FLORIN, Lawrence, B. [US/US]; 1405 Ringneck Loop, Dresher, PA 19025

(US). HASPIEL, Joseph, B. [US/US]; 17 Arbor Road, St. Louis, MO 63132 (US). CONVERSE, Lance [US/US]; 39 High Gate Lane, Blue Bell, PA 19422 (US). ROSENBERG, Leonard [US/US]; 735 Lippincott Avenue, Moorestown, NJ 08057 (US). MICHELSON, Leslie, Dennis [US/US]; 804 North Whittier Drive, Beverly Hills, CA 90210 (US). JAMES, Steven, P. [US/US]; 13292 Seagrove Street, San Diego, CA 92130 (US).

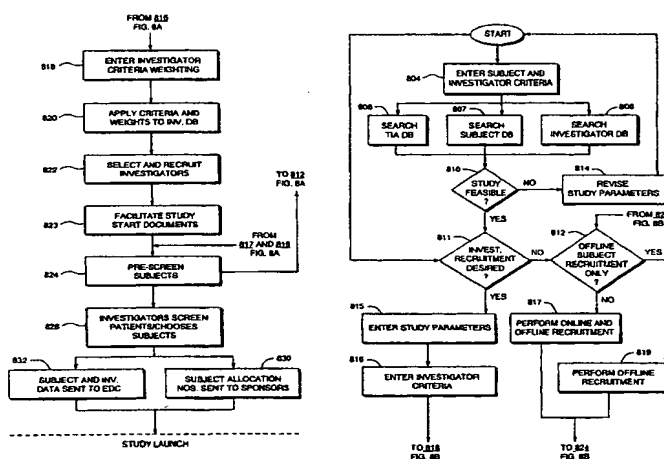
(74) Agents: MICALLEF, Joseph A. et al.; Arnold &amp; Porter, 555 12th Street, NW, Washington, DC 20004 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,

[Continued on next page]

(54) Title: SYSTEMS AND METHODS FOR SELECTING AND RECRUITING INVESTIGATORS AND SUBJECTS FOR CLINICAL STUDIES



(57) Abstract: The present invention is directed to an integrated on-line interactive forum that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subjects. The forum includes an investigator database (808) that contains information suitable for identification of qualified investigators (811) for clinical studies and a subject database (807) that contains information suitable for identification of eligible subjects for clinical studies (817, 819). An extranet is coupled to the investigator database and the subject database. The extranet allows sponsors and investigators to exchange securely documents required to start a clinical study (830). The forum also optionally includes one or more web pages that provide information describing clinical studies to potential clinical study subjects and permit potential clinical study subjects to register for inclusion in the subject database. A therapeutic incidence area database (806) is also optionally integrated into the forum.

WO 01/055942 A1



IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**(15) Information about Correction:**

see PCT Gazette No. 44/2002 of 31 October 2002, Section II

**Published:**

— *with international search report*

**(48) Date of publication of this corrected version:**

31 October 2002

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

SYSTEMS AND METHODS FOR SELECTING AND RECRUITING  
INVESTIGATIONS AND SUBJECTS FOR CLINICAL STUDIES

Cross-Reference To Related Application

5           The present application claims priority to U.S. provisional application no. 60/178,634, filed January 28, 2000, entitled "Method and System for Creating And Managing Databases for Clinical Trials," the contents of which are hereby incorporated herein in their entirety by reference.

Field of the Invention

10           The present invention relates to a novel integrated on-line interactive forum that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subjects. In addition, the present invention relates to novel systems and methods for selecting and recruiting subjects and investigators for clinical studies.

15                           Background of the Invention

          The increase in the breadth and specificity of research and development for the purposes of identifying and qualifying new drugs and devices for a wide variety of therapeutic areas has resulted in an increase in the specificity and number of subjects and qualified investigators needed by medical and pharmaceutical companies to participate in  
20   clinical studies.

          Recruitment of a number of clinical study subjects sufficient to establish the safety and efficacy of a drug or device on specific clinical subject populations is essential for the success of clinical study, and therefore for the obtaining of the regulatory approvals necessary for marketing the drug or device on a world wide basis. Recruiting clinical

subjects has been complicated by, among other things, the specificity of the new therapies, the increase in the number and breadth of clinical studies required by regulatory authorities, and the globalization of the clinical trial process.

5 The increased complexity of therapies, primarily the result of advances in the application of biotechnology and combinatorial chemistry, has resulted in increased requirements for additional clinical studies from regulatory agencies. In addition, the requirements of managed care companies for more additional outcome information results in a growing demand for clinical studies. This, in turn, increases the pressure to identify adequate numbers of clinical subjects and qualified clinical investigators. Where  
10 traditionally a large number of the clinical studies in a particular therapeutic area were conducted by a small number of clinical investigators, the increase in demand makes it necessary for additional physicians to become trained in the conduct of clinical trials, new means to be developed to recruit subjects, and a broadening of the scope of the search for qualified clinical investigators.

15 The increased complexity of therapies has been marked by a trend away from the mass treatment mentality of the past, toward treatment of an individual based on the individual's specific characteristics. For example, new therapies are being developed that are specifically designed to interface with an individual's genome. This necessitates the use of clinical subjects that share certain genetic characteristics. This means that the  
20 pool of clinical subjects is naturally smaller, and creates a need to draw from a broader base of individuals in order to identify sufficient numbers of eligible participants to complete a clinical study. Handling of the sensitive information identifying an individual's potential genetic propensities implicates certain privacy issues, and add an

additional layer of complication to the clinical study recruitment process. Many subjects are concerned that if, for example, they are found to have a particular genetic propensity for certain diseases in the course of a study that they may have difficulty obtaining health coverage.

5           The result of the foregoing has been an increase in the number of clinical studies, and hence the need to identify qualified investigators and eligible individuals, in geographic locations other than the country wielding regulatory authority. The ability to advance a clinical study simultaneously in many locations, and locating qualified investigators and eligible subjects, increases the likelihood that the clinical study will be  
10       completed with minimal delays. Delays are extremely costly to clinical study sponsors because each day a new drug is delayed from reaching the market results in lost revenue and, potentially, lost exclusivity and a later market entry. Delays and the high costs associated with launching a clinical study are some of the biggest obstacles to bringing a new drug to market.

15           Thus, there exists a need to provide a global means to facilitate the identification and communication between clinical sponsors, clinical investigators and eligible clinical subjects to expedite the process of launching clinical studies in an efficient and cost-effective manner.

#### Summary of the Invention

20           The present invention is directed to an integrated on-line interactive forum that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subjects. The forum includes an investigator

database that contains information suitable for identification of qualified investigators for clinical studies sponsored by the sponsors, and a subject database that contains information suitable for identification of eligible subjects for clinical studies sponsored by the sponsors. An extranet is coupled to the investigator database and the subject database.

- 5 The extranet permits the secure exchange between sponsors and investigators of documents required prior to the start of a clinical study. The forum also optionally includes one or more web pages that provide information describing clinical studies to potential clinical study subjects and permit potential clinical study subjects to register for inclusion in the subject database. A therapeutic incidence area database is also optionally
- 10 integrated into the forum.

The present invention is also directed to a method for recruiting a person to participate as a subject in a clinical study. One or more web pages are presented that allow the person or a caregiver associated with the person to register with a database by submitting registration and permission information to the database. The registration information

15 includes, for example, a user id, a password, preferred contact information (i.e., an electronic mail address or telephone number), zip code, first name or preferred name, gender, date of birth, whether the person or caregiver is interested in clinical study information, and whether the person or caregiver is interested in new medical therapies. The permission information includes whether the person or caregiver is interested in

20 receiving notice of clinical studies. The person or caregiver is automatically registered with the database upon receipt of the registration and permission information. Next, an automatic determination is made, in accordance with the permission information and the registration information, as to whether to provide the person or caregiver with notice of a

given clinical study associated with a disease condition of interest to the person. The person or caregiver is provided notice of the given clinical study only if the system automatically determines that such notice should be sent. A questionnaire associated with the given clinical study may also be provided automatically to the person or caregiver, if the person or caregiver indicates interest in the clinical study in response to the notice. Answers submitted by the person or caregiver to the questionnaire are then stored in the database. The stored questionnaire answers, along with other information stored in the database, may be accessed to determine whether the person should be pre-screened for participation as a subject in a clinical study different from the given clinical study.

In another embodiment, the present invention is directed to a further method for identifying subjects eligible to participate in a clinical study. A computer database that stores information about a plurality of persons is accessed. For each person listed in the database, the database includes a geographic location of the person, an age and a gender of the person, medications taken by the person, and disease conditions of interest to the person. A query is submitted to the database. The query includes criteria that reflect eligibility characteristics for persons suitable for use as subjects in the clinical study. De-identified data records of persons likely to be subjects eligible for the clinical study are selected based on the query. The feasibility of the clinical study may next be evaluated based on the de-identified data records returned from the query. The feasibility of the study can then be further explored by modifying the criteria used to query the database and repeating the above steps using the modified criteria.

The present invention also includes a method for identifying a qualified investigator to perform a clinical study. At least one computer database that stores a

geographic location of each of a plurality of investigators is accessed. The at least one database also stores an incidence or a prevalence of each of a plurality of disease conditions in each of a plurality of different geographic locations. At least one query that includes information representing a selected disease condition associated with the clinical study is submitted to the at least one database. The qualified investigator is identified from the at least one database based on the query and in accordance with the incidence or prevalence of the selected disease condition in the geographic location of or proximate to the qualified investigator.

The present invention includes a further method for identifying a qualified investigator to perform a clinical study. In this further method, at least one computer database stores a geographic location of each of a plurality of investigators is accessed, wherein the database also stores a geographic location of subjects proximate to each of the plurality of investigators. A query that includes information representing a selected disease condition associated with the clinical study is submitted to the at least one database. The qualified investigator is identified from the at least one database based on the query and in accordance with the geographic location of subjects proximate to the qualified investigator. The at least one database also optionally stores an incidence or a prevalence of each of a plurality of disease conditions in each of a plurality of different geographic locations, and the qualified investigator is identified from the database based also on the incidence or prevalence of the selected disease condition in the geographic location of the qualified investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores



information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the prescription writing history of the investigator with respect to a plurality of medications. The database also optionally stores information that associates each of the medications  
5 with one or more disease conditions. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the given investigator's prescription writing history.

The present invention is directed to a still further method for identifying  
10 investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the history of laboratory procedure requests made by the investigator. The database also optionally  
15 stores information that associates each of the laboratory procedure requests with one or more disease conditions. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the given investigator's history of laboratory procedure requests.

The present invention is directed to a still further method for identifying  
20 investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to past participation of the investigator in clinical studies. A query that may include information

representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the given investigator's past participation in clinical studies.

The present invention is directed to a still further method for identifying

5 investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to a medical specialty of the investigator. The database also optionally stores information that associates each medical specialty of an investigator with one or more disease conditions.

10 A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the given investigator's medical specialty.

The present invention is directed to a still further method for identifying

15 investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the experience of the medical staff of the investigator. A query that includes information representing a selected disease condition associated with the study is submitted to the

20 database. A given investigator is identified from the database based on the query and in accordance with the experience of the medical staff of the investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores

information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to a hospital affiliate of the investigator. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given

5 investigator is identified from the database based on the query and in accordance with the given investigator's hospital affiliation.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each  
10 investigator listed in the database and includes information corresponding to claims data of the investigator. The database also optionally stores information that associates claims data of the investigator with one or more disease conditions. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on  
15 the query and in accordance with the given investigator's claims data.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the number  
20 of beds in the hospital affiliate of the investigator. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the number of beds in the hospital affiliate of the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the insurance provider affiliations of the investigator. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the insurance provider affiliations of the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to any Institutional Review Board ("IRB") affiliation of the investigator. The database also optionally stores information that associates each IRB. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the mandated IRB relationships of the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to FDA or other regulatory agency audits of the investigator. A query that includes information representing a selected disease condition associated with the study is submitted to the

database. A given investigator is identified from the database based on the query and in accordance with regulatory agency audits of the investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to any Primary Research Facility ("PRF") affiliation of the investigator. The database also optionally stores information that associates each PRF affiliation. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the PRF affiliations of the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to equipment available to the investigator. The database also optionally stores information that associates various pieces of equipment with one or more disease conditions. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is identified from the database based on the query and in accordance with the equipment available to the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores

information on a plurality of investigators is accessed. A data record is stored for each investigator listed in the database and includes information corresponding to the practice setting of the investigator. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given  
5 investigator is identified from the database based on the query and in accordance with the practice setting of the given investigator.

The present invention is directed to a still further method for identifying investigators qualified to perform a clinical study. A computer database that stores information on a plurality of investigators is accessed. A data record is stored for each  
10 investigator listed in the database and includes information corresponding to the investigator's city and state of practice. A further database also optionally stores information that associates the investigator's city and state of practice with one or more disease conditions. A query that includes information representing a selected disease condition associated with the study is submitted to the database. A given investigator is  
15 identified from the database based on the query and in accordance with the investigator's city and state of practice.

The present invention is also directed to a method for developing a permission based online database. One or more web pages are presented that allow a person to register with a database by submitting registration and permission information to the  
20 database. The registration information includes name information and contact information and the permission information indicates whether the person wishes to receive notice of one or more clinical studies. The person is automatically registered with the database upon receipt of the registration and permission information. Permission is obtained to

send the person marketing information about drugs, medical devices or medical therapies. The database is added to by repeating the above steps for a plurality of persons. Next, a list is generated for use in marketing drugs, medical devices and medical therapies to subjects by querying the database using criteria associated with the drugs, medical devices  
5 and medical therapies.

The present invention is also directed to a method of maintaining the confidentiality of clinical study information associated with a plurality of clinical study sponsors. Clinical study information is received from a plurality of clinical study sponsors, and stored in a database. Each sponsor is permitted full access in the database  
10 to clinical study information submitted by that sponsor. Each sponsor is permitted limited, de-identified aggregated access to information submitted by other sponsors. The clinical study information submitted by each sponsor optionally includes any combination of: investigator information, sponsor identification, protocol information, drug indication information, drug class information, clinical study enrollment goal information, actual  
15 clinical study enrollment information, and information on the number of clinically evaluable subjects.

#### Brief Description of the Drawings

Fig. 1A is a block diagram showing the connection over a computer network of additional computers to the integrated, on-line interactive forum of the present invention.

20 Fig. 1B is a block diagram showing the components of the integrated, on-line interactive system of the present invention.

Figs. 2A and 2B depict an exemplary Internet web page used for registering persons in a database used for identifying eligible subjects for a clinical study, in accordance with the present invention.

Fig. 3 depicts an exemplary web page used by a person to submit geographic and contact information to a database used for identifying eligible subjects for a clinical study, in accordance with the present invention.

Figs. 4A, 4B, 4C and 4D depict an exemplary web page through which a person submits one or more disease conditions of interest to a database for identifying eligible subjects for a clinical study, in accordance with the present invention.

Figs. 5A through 5J depict an exemplary web page which conveys to a registered user information about clinical studies, in accordance with the present invention.

Figs. 6A through 6R depict a series of exemplary web pages through which a person can search clinical studies and opt to receive information about clinical studies in one or more selected therapeutic areas, in accordance with the present invention.

Figs. 7A through 7E depict an exemplary web page that provides a questionnaire that may be completed by an investigator interested in conducting a clinical study, in accordance with the present invention.

Fig. 7F to 7J depict flow diagrams showing processes for registering subjects and investigators, in accordance with alternative embodiments of the present invention.



Figs. 8A and 8B is a flow diagram showing the steps performed by a sponsor using the professional site to recruit subjects, investigators, and take steps necessary to start a clinical study.

5 Figs. 9A and 9B is an exemplary web page used by a sponsor to enter study parameters into the system.

Figs. 10A and 10B is an exemplary web page used by a sponsor to enter criteria necessary to initiate an investigator search.

Figs. 11A and 11B depict an exemplary web page showing the search results from an investigator search performed using the present invention.

10 Figs. 12-13 are exemplary web pages showing an extranet for creating, sending and tracking documents necessary to start a clinical study.

Figs. 14 is an exemplary electronic mail notification used for contacting a potential subject for a clinical study.

15 Fig. 15A through 15H is an exemplary study-specific subject questionnaire used for prescreening a subject for a clinical study.

Fig. 16 is a process flow diagram showing the steps of a method for identifying persons to participate in a clinical study, in accordance with a further embodiment of the present invention.

20 Fig. 17 is a process flow diagram of a method for identifying eligible investigators for a clinical study, in accordance with one embodiment of the present invention.

Fig. 18 is a process flow diagram showing the steps of a method for identifying eligible investigators for a clinical study, in accordance with an alternate embodiment of the present invention.

Fig. 19 is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study, in accordance with a still further embodiment of the present invention.

Fig. 20 is a process flow diagram showing the steps of a method for recruiting a  
5 person to participate in a clinical study, in accordance with the present invention.

Figs. 21A – 21Q show the steps of various methods of recruiting investigators in accordance with alternative embodiments of the present invention.

Figs. 22A through 22K depict an exemplary data structure for implementing an investigator database, in accordance with the present invention.

10 Figs. 22L-P depict use of a disease incidence search on a TIA database to assist in performing investigator and subject selection, in accordance with the present invention.

Fig. 23 is a screen shot showing sponsor access limitations to study data.

Figs. 24A through 24E depict an exemplary data structure for implementing a subject database, in accordance with the present invention.

15 Fig. 25 depicts an exemplary data structure for implementing a study listings database, in accordance with the present invention.

Figs. 26A and 26B depicts an exemplary data structure used for implementing the sponsor access limitations shown in Fig. 23.

20 Fig. 27 is a flow diagram of a method for performing permission-based electronic mail marketing to consumers, in accordance with the present invention.

Detailed Description of the Preferred Embodiment

For purposes of the present invention, each of the terms set forth below shall be defined in accordance with the corresponding definitions set forth below:

“Clinical Investigator” or “Investigator” shall mean the Person with regulatory  
5 responsibility for conducting a Clinical Study.

“Clinical Study(ies)” shall mean studies designed to distinguish the effect(s) of a drug or a medical device on humans from other influences--for example, a spontaneous change in disease progression or in the effect of a placebo (an inactive substance that looks like the test drug).

10 “Clinical study sponsor” or “sponsor” shall mean any person responsible for conducting or overseeing a clinical study or trial, including, without limitation, pharmaceutical companies, clinical research organizations, biotechnology companies, medical diagnostic companies, medical device companies or other entities.

15 “Clinical Subject” or “Subject” shall mean the human subject of a Clinical Study or a potential human subject of a Clinical Study.

“Clinical trials” shall mean those clinical studies required to achieve regulatory approval.

20 “Consent Information” shall mean that information required by applicable law and/or regulation in order to properly consent to the disclosure of confidential subject information.

“Contract Research Organization” or “CRO” shall mean an organization that receives services relating to conduct of clinical studies.

“Disease Condition” means any human disease or condition for which a Clinical Study may be conducted, including without limitation, a physiological, physical,

psychological, psychiatric, surgical or post-surgical condition, whether or not manifest by symptoms. It also includes conditions definable by the existence or omission of a particular genotype, phenotype, or other genetic structure or ordering of genetic material.

“Electronic data capture” or “EDC” shall mean a company in the business of  
5 providing software that collects data through the conduct of a clinical study.

“Extranet” shall mean a web application that works over the Internet for sharing data with specific users. Access to the application is protected by the use of passwords, encryption and other security mechanisms.

“Identifying Information” shall mean any individually identifiable health  
10 information transmitted in the course of recruiting clinical subjects that relates to an individual’s physical or mental health or condition, and/or the provision or payment of care, and that identifies the individual or creates a reasonable basis to believe the information can be used to identify the individual.

“De-identified Data” shall mean data in which identifying information has been  
15 removed or hidden by removing, coding, encrypting, or otherwise eliminating or concealing the information such as name, address, birth date, name of relatives or employers, telephone numbers, email address and other unique identifying numbers, characteristics or codes that the covered entity had reason to believe may be used by an anticipated recipient of the information to identify the individual.

20 “IRB” shall mean “Institutional Review Board”. Other countries may have equivalent such ethics boards under International Health Commission (“IHC”) guidelines.

“Investigational Drug or Device” shall mean any drug or device that is the substance or object being tested in a Clinical Study; including without limitation, drugs or

devices designed for the cure, prevention, control, monitoring of treatment or treatment of a Disease Condition.

“Laws” shall mean all applicable laws, statutes, rules, regulations, ordinances and other applicable pronouncements having the effect of law whether federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign which pertain to and are applicable to the disclosure of confidential subject information including subject identity.

“Permission Information” shall mean optional information submitted by a user of a database in order to convey the user’s agreement to receive data or information or to have personal and/or confidential information provided by the user disclosed under certain defined circumstances.

“Person” shall mean any individual, corporation, partnership, association, unincorporated organization or government or political subdivisions thereof.

“Primary research facility” or “PRF” shall mean the location at which the investigator conducts a clinical study.

“Regulatory Approval” shall mean, with respect to a country, all authorizations by the appropriate governmental entity or entities necessary for commercial sale of a drug product in that country including, without limitation and where applicable, approval of labeling, price, reimbursement and manufacturing. “Regulatory Approval” in the United States shall mean final approval of a new drug application pursuant to 21 C.F.R. § 314, permitting marketing of a drug product in interstate commerce in the United States.

### System Architecture

Referring first to Figure 1A, in that figure is depicted computer network 103 operatively connecting computer system 100 to more or more additional computer systems represented here as computer systems 101 and 102. Computer system 100,  
5 described in more detail below, may be any of a number of commercially available computer systems, including a conventional server or workstation. Such systems may include, for example, one or more microprocessors, computer memory, conventional communication circuitry (e.g., a modem) and other commonly available peripherals. Computer systems 101 and 102, and other computers that interface with network 103, may  
10 also be such workstations or servers, or may comprise any type of commercially available personal computers capable of communicating over a computer network. Those of ordinary skill in the art will recognize that network 103 may connect to any number of additional computers. Network 103 represents a public or private computer network. The Internet is one example of such a network, though other types of networks are possible  
15 within the scope if the inventions described herein.

Referring now to Figure 1B, there is shown a block diagram of an integrated online system 100 that promotes exchange of information among clinical study sponsors, clinical study investigators, and clinical study subjects, in accordance with the present invention. The clinical study sponsors, investigators and subjects may access system 100  
20 using computers such as computers 101, 102. Among other things, system 100 serves to integrate the now fragmented clinical study system by bringing clinical study sponsors, clinical study investigators, and subjects together in a common environment. The system 100 also serves to integrate the clinical study system by bringing the clinical study sponsors, clinical study investigators and subject's data together in a secure environment.

In addition, and as discussed more fully below, system 100 includes specialized databases and collaboration tools that allow clinical study sponsors and investigators to take the steps necessary to start a clinical study more quickly, including assessing the feasibility of a study, locating qualified investigators, communicating with investigators, completing all  
5 required preliminary documentation necessary to enroll investigators in the study, locating qualified and interested subjects, communicating with interested subjects, and directing interested subjects to appropriate investigator sites to perform the physical assessment and complete the necessary documentation to enroll the subjects in the clinical study.

System 100 contains several databases, that function in combination to facilitate  
10 the start of a clinical study. By way of an overview, system 100 includes a subject database that includes information about persons that may potentially qualify as eligible subjects for a clinical study. Demographic information about each registered person is stored in the subject database. In addition, information about disease conditions of interest to persons in the subject database and information about clinical studies of interest  
15 to such persons is stored in the subject database. As a potential subject interacts with system 100 over time by, for example, attempting to qualify for participation in various clinical studies, system 100 collects and stores additional information about the persons represented in the subject database. In accordance with this aspect, individual subjects or their caregivers will enter information about themselves into system 100 when they  
20 attempt to qualify for a given clinical study. This information may be limited to what is sought in the registration questionnaire, or it may take the form of responses to one or more different questionnaires designed to assess eligibility for a given clinical study. Irrespective of whether the subject is ultimately selected for participation in the study, upon obtaining appropriate consent from the subject, the information entered by the

subject during any pre-screening for the clinical study will be added to the registration information and stored as part of the subject database. Over time, as a given individual attempts to qualify for further clinical studies, still further information will be collected about the individual in connection with the screening for the further clinical studies. This  
5 further information will also be stored in the subject database. Thus, over time, the information in the subject database will grow more detailed and complete as the same individual provides additional information to apply for additional studies using system 100. As discussed more fully below, the subject database is used by clinical study sponsors to identify potential subjects to participate in clinical studies. As the information  
10 stored in the subject database becomes more detailed and complete over time, the utility of the subject database will be further enhanced from the point of view of clinical study sponsors because the sponsors will be able to identify more rapidly, accurately and with higher confidence potential subjects for their clinical studies.

In system 100, potential clinical study subjects submit data (later stored in the  
15 subject database) through the subject site. The subject site is, for example, an internet website that is accessible to the general population. Further details of the subject site are shown in Figs. 2 through 6, and discussed below. By way of overview, the subject site includes content about new medical therapies and current clinical studies. This content is typically of interest to chronically ill persons, persons who are newly diagnosed with a  
20 particular illness, caregivers for persons with a particular illness, and other persons in the general population who might be interested in participating as subjects in a clinical study. The content is preferably available for free to the users. However, when viewing the content, users are requested to register with the subject site. During the registration process, a given user will enter demographic information about himself or herself, and



will be given an opportunity to indicate areas of new medical therapies or clinical studies that are of interest to the individual. All such information entered by the user is stored in the subject database. As discussed more fully below, if a registered user wishes to attempt to qualify for participation in a clinical study, the individual may submit answers to a questionnaire tailored to the clinical study via the subject site. (In one embodiment, the questionnaire answers are received from the subject or caregiver on a secure page of the subject website.) These questionnaire answers are then used for at least three purposes. First, the answers are used to pre-screen the individual for the given clinical study for which they are attempting to qualify. Second, with appropriate consent from the individual, the questionnaire answers are stored in the subject database and used to assess more accurately whether or not the given individual would be appropriate for consideration in a later clinical study. Third, the questionnaire answers are used to assess the feasibility of subsequent studies. Fourth, the answers may be used to lock-out people once they are in a study.

Referring still to Figure 1, system 100 also includes an integrated investigator database. In one embodiment, the investigator database includes information from three general sources as described below, although in other embodiments it may include information from a lesser or greater numbers of sources or different sources. First, the investigator database includes data about the clinical study investigators who wish to inform clinical study sponsors of their clinical study experience and/or training, submitted by the investigators themselves. This self-reported data is typically entered into the investigator database either when a given investigator logs onto the professional site, and registers with the system as described further with reference to Figs. 7A through 7E or by submitting such information to the professional site by mail, fax, phone or other non-

computerized means. The self-reported data includes various types of information including, for example, the educational background of the investigator, the clinical study experience of the investigator, the past performance of the investigator in other clinical studies (e.g., how many subjects the investigator committed to recruit for a given study in  
5 what period of time, how many subjects the investigator actually recruited for the study in what period of time, and how many of such subjects actually completed the study), equipment available to the investigator (e.g., whether or not the investigator has access to a CAT scan machine or MRI equipment which may be required for a given study), any mandated IRB relationships of the investigator (e.g., whether or not the investigator is  
10 required through professional affiliations to submit materials to a particular IRB for approval before the materials may be used to advertise the study), any hospital or HMO affiliations of the investigator, information about the investigator's staff and facilities and the geographic location of the investigator.

In addition to the self-reported information, the investigator database also includes  
15 information about investigators received from a variety of external sources. One such external source is the FDA, which can provide information about any past clinical studies for which an investigator has registered, as well as any information about sanctions or other disciplinary actions that may have been issued in connection with an investigator's work in a past clinical study. Information obtained from the investigator in the past or  
20 from other third party sources, such as an investigator's prescription writing history and the history of laboratory requests made or lab results received by an investigator in the past, are stored in the investigator database. Such external information can be used to both supplement and verify the self-reported data entered by the investigator and discussed above. Clinical study sponsors may also supply information about their past

experiences with a given investigator, and such information may be stored in the investigator database.

In addition to the self-reported and external source data, additional information about a given investigator will be learned by system 100 as the investigator interacts with system 100 and attempts to enroll in clinical studies with the assistance of the system. For example, in some embodiments, after a given clinical investigator has been recruited for a given clinical study using system 100, the system will monitor the investigator's performance with respect to the clinical study and store this performance data in the investigator database if the system is linked to an EDC product that is collecting data throughout the study. In alternative embodiments, the performance data may be obtained through off-line sources.

In an embodiment, system 100 also includes a Therapeutic Incidence Area ("TIA") database. The TIA database contains the incidence and/or prevalence of different disease conditions by geographic area. Thus, for example, the TIA database may store the incidence or prevalence of colon cancer in each of several different municipalities across the country. The data sets and search parameters used to conduct searches in the TIA databases have been created to conform to the information required by clinical study sponsors when determining the likelihood of recruitment success within the projected time frame for a particular protocol for the study, or when determining where to locate investigator sites to conduct the study. As explained more fully below, the present invention uses the TIA database to assist in the selection of investigators for a given clinical study by searching for an investigator who is proximate to a geographic area where a greater number of subjects who may be eligible to participate in the study reside or receive treatment.

An important part of system 100 is its incorporation of an extranet to facilitate secure collaborations between a clinical study sponsor (or its designees) and its investigator(s) during the process leading up to the start of a clinical study. As discussed more fully below, after a clinical study sponsor has identified an investigator to perform a given

5 clinical study, the sponsor must formally engage the investigator for the study. During the engagement process, several documents (e.g., an investigator questionnaire, answers to the investigator questionnaire, a confidentiality agreement, a contract, a budget, an FDA form 1572, IRB documents, the study protocol, etc.) will in most instances be exchanged between the sponsor and the investigator. The present invention provides a secure

10 environment for these communications, as well as functionality that manages and tracks the documents needed to start the clinical study. In one embodiment, this functionality is achieved by allocating individual workspaces to sponsors and investigators within the professional site. A given sponsor or investigator is then able to receive, send, and track documents from within his or her workspace.

### Subject Site and Registration

Information regarding potential clinical study subjects may be gathered from a variety of different sources including, in a preferred embodiment, via a web site such as subject site of Fig. 1B. The information obtained regarding potential clinical study subjects must be sufficiently general in nature such that it may be applicable to a variety

20 of different therapeutic areas and disease conditions, yet specific enough to be useful in assessing the subject's eligibility for a specific study with narrowly defined inclusion or exclusion criteria.

Figs. 2A and 2B depict an exemplary internet web page, which allows for the registration of persons in a database (e.g., the subject database of Fig. 1B) and which is

used for identifying eligible subjects for a clinical study, in accordance with the present invention. Registration web page 200 includes e-mail area 201, username area 202, and password area 203 where the person registering in the database may enter his or her information. A hypertext link 204 to a privacy and security policy of the service provider  
5 may be provided in some embodiments. In all embodiments, the privacy of subjects is protected by ensuring compliance with all applicable laws. A question/answer area 205 may be provided for use in the event the person forgets his or her password. In agreement area 206, the terms and conditions pursuant to which the person is entitled to register himself or herself in the subject database and use the inventive system may be provided.

10 Fig. 3 depicts an exemplary web page of subject site used by a person to submit geographic, gender and contact information to a database, such as the subject database of Fig. 1B, used for identifying eligible subjects for a clinical study, in accordance with the present invention. Personal information web page 300 includes name, contact information, and geographic information area 301 as well as gender information area 302  
15 where the person registering in the database enters his or her information.

Figs. 4A through 4D depict an exemplary web page of subject site through which a person may submit one or more disease conditions to a database for identifying eligible subjects for a clinical study, in accordance with the present invention. Therapeutic area web page 400 includes pull down menu 401 at which a person may identify a therapeutic  
20 area of interest to that person. In this example, the therapeutic area cancer has been chosen. Upon clicking on view button 402, the potential disease conditions of interest are presented to the subject or caregiver in disease condition area 403. The person may check one or more boxes in medical news/drug area 404 or clinical study opportunities area 405 to indicate if the person is interested in obtaining medical news, drug or clinical study

opportunity information on any of the disease conditions specified in disease condition area 403.

Figs. 5A through 5J depict an exemplary web page of the subject site, which conveys information about clinical studies, and an ability to search clinical studies to a registered user, in accordance with the present invention. Frequently asked questions area 503 is provided to educate a person on clinical studies. In search area 501, the registered user may click on any one of the therapeutic areas identified (such as cancer clinical study area 502) and be taken to a search clinical study web page 600, as depicted in Figs. 6A and 6B.

Search clinical studies web page 600 allows the user to search for clinical studies relating to the therapeutic area identified in search area 501. Search clinical study web page 600 includes search area 601 which allows the user to use particular search criteria to find clinical studies. For example the user may select a condition in condition area 602 and/or may select a state in location area 603. The user may also select a particular geographic location, in location area 603. The user may indicate in contact area 604 that the person wishes to be contacted for a particular clinical study.

Upon clicking on contact area 604, the user will be taken to general study interest web page 605 shown in Figs. 6C and 6D. On general study interest web page 605, the registered user may indicate in interest area 606 whether the registered user is interested for himself/herself or for someone else. In one embodiment, the registered user may select in selection area 607 up to three therapeutic areas in which the registered user is interested. In contact area 608, the registered user indicates the manner in which the registered user would like to be contacted, e.g., by e-mail, telephone or regular mail. The registered user also indicates name and contact information in contact information area

609. The registered user submits the form by clicking on submit button 610, or may cancel the process by clicking on cancel button 611.

In other embodiments, the above-referenced information may be included in the database and entered via the web site not by the subject but by a caregiver of the subject.

5 The caregiver may be anyone who is providing care to the subject, such as a medical professional, a family member, or a friend.

In an alternative embodiment, in order to become a user registered with the subject database, the user will be required to provide the information required as shown in the web page depicted in Fig. 6E: a user id; password; password reminder; and whether the  
10 user is seeking information for himself or herself or for someone else. In a second step, with reference to Figs. 6F and 6G the user will be required to provide additional information such as first name, date of birth, gender, electronic mail address, zip code and an indication of one or more medical conditions in which the user is interested. Additional information, though not required for registration, may be provided such as  
15 medical conditions experienced by the user, salutation, last name, ethnic background, telephone number, country of residence, as shown in Figs. 6F and 6G. In a third step 3, the user inputs information on a web page such as that shown in Fig. 6H, including a request to receive various types of information (such as, e.g., clinical study opportunities or news and new medical therapies) about the user's medical conditions identified in Figs.  
20 6F and 6G. The user may request that he or she not be sent any information. In area 650, the user is asked to agree to certain terms and conditions governing the user's use of the inventive system.

Upon completing the required information and accepting the terms and conditions, the user will become a registered user of the inventive system, as shown in the web page

depicted in Fig. 6I. At this point, the user may choose to answer additional, optional questions or to return to the previous activity. If the user chooses to answer additional questions, the user may be taken to a web pages such as those depicted in Figs. 6J through 6N and provide information such as the type of prescriptions or over-the-counter

5 medications taken by the user for a given medical condition; the health habits of the user; and the clinical study experience of the user. In Fig. 6O, the user can see if the user has answered completely questions about each medical condition previously listed by the user. In Fig. 6P, the user can provide feedback. In Fig. 6Q, the service provider may provide a thank you to indicate that the message was sent successfully.

10 The registered user may also access, on the subject site, the registered user's own personal library. Library web page 612, shown in Fig. 6R, informs the registered user that he or she may maintain a personal library of information relating to clinical studies or new developments related to particular therapeutic areas found throughout the subject site. The user may also create and save personal notes relating to the same. Information may  
15 be placed in the library by the registered user or, in some embodiments, specific information on topics which may be of interest to the registered user may be placed in the registered user's library automatically based on, for example, the registered user's past selections of information to place in the library, therapeutic areas of interest, disease conditions of interest, geographic location, and/or gender.

20 **Investigator Registration on Professional Site**

An investigator who is interested in conducting clinical studies may express his or her interest by registering on the professional site of Fig. 1B. Figs. 7A, 7B, 7C, 7D and 7E depict investigator questionnaire web page 700 that provides a questionnaire that may be completed by an investigator interested in conducting a clinical



study, in accordance with an embodiment of the present invention. In name area 701, the investigator is required to input his or her name. In degree area 702, the investigator's degree(s) are required. The PRF organization or institutional name, address, city state, country, zip code and telephone number are required (and fax and electronic mail address optionally requested) in contact area 703. Specialty area 704 requires that the investigator provide his or her primary specialty area. Board area 705 requires that the investigator indicate whether he or she is board certified and/or board eligible; optionally, the investigator's year of primary specialty board certification, and board information regarding any of the investigator's subspecialties may be provided. In study experience area 706, the investigator is required to indicate the number of years the investigator has participated in clinical studies as well as all phases of clinical research in which the investigator has participated. The investigator must include the number of investigators that conduct research at the PRF indicated in investigator area 707.

Additional information may also be provided regarding, for example, the following: the IRB with which the investigator is associated, as indicated in IRB area 708; any audits of the investigator conducted by the FDA or other regulatory agency, as indicated in FDA audit area 709; any audits of the investigator conducted by a sponsor or CRO, as indicated in sponsor audit area 710; and/or information about the investigator's PRF, such as whether it is single specialty, multi-specialty, part of a solo or group practice, or affiliated with a site management organization or research group, as indicated in PRF area 711. In alternative embodiments, an investigator provides the information requested in the investigator questionnaire by phone, fax, regular mail or other non-computerized means, rather than transmitting the information to the professional site online.

In addition to the information described above, an investigator may be required to include information regarding his or her publications and educational background; hospitals or PRF with which the investigator is associated; health plans with which the investigator is associated; equipment to which the investigator has access; and any sanctions imposed by the FDA or other regulatory agency upon the investigator.

#### **Alternative Embodiments For Subject and Investigator Registration**

Fig. 7F to 7J depict flow diagrams showing processes for registering subjects and investigators, in accordance with alternative embodiments of the present invention. Fig. 7F is directed to persons that register with the subject or investigator site based on a visit to the subject site; Fig. 7G is directed to persons that register with the subject or investigator site based on a contact with a pharmaceutical call center; Figs. 7H and 7I is directed to persons that register with the subject or investigator site based on a contact with an off-line call center; and Fig. 7J is directed to persons that register with the subject or investigator site based on a visit to a third party on-line recruitment site.

#### **Study Feasibility and Launch Process**

Referring now to Figures 8A and 8B, there is shown a flow diagram of a process that may be used by a sponsor to accomplish the steps necessary to start a clinical study. The process may begin at two different points. Specifically, if the sponsor wishes to begin by making a feasibility assessment with respect to the study, the process starts at step 804. Alternatively, if the sponsor does not wish to make a feasibility assessment, the process starts at step 811.

In step 804, the sponsor enters various criteria necessary to identify potential subjects and/or investigators for the study into the system. These criteria include, for example, criteria that determine which subjects may be included or excluded from the

study, one or more specialties that an investigator for the study should have, information about the prescribing behavior of the investigator, the number of studies that the investigator should have conducted, the therapeutic area and disease indication associated with the clinical study, the distance around the investigator site in which subjects  
5 participating in the study should be found, and the geographic area in which the investigator should be found.

Next, in steps 806, 807 and 808, various criteria from step 804 are applied to the TIA, subjects and investigator databases in order to assess the likelihood that sufficient subjects will be available for the study, and to assess the likelihood that a sufficient number of  
10 suitable investigators will be available for the study. In applying the subject criteria to both the TIA and subject database, the present invention is able to both identify subjects in the subject database that may be appropriate for the clinical study (this information comes from the subject database), and also identify geographic areas where incidences of the relevant diseases or conditions are more prevalent (this information comes from the TIA  
15 database.) By querying the TIA database for this disease incidence/prevalence information, the system is able to identify geographic areas where potential subjects (not listed in subject database) may be more likely to be found using off-line and/or on-line recruiting not involving the subject database. In addition, the geographic locations of investigators who may qualify for the study are compared against the TIA search results  
20 and the search results from the subject database (specifically, the locations of such subjects) in order to identify investigators with the highest likelihood of fulfilling the enrollment requirements of the study because they are located proximate to where there are the largest numbers of suitable subjects. This aspect of the assessment process recognizes that, in the case of some studies, potential subjects may be unwilling to travel

any significant distance to participate in the study, while, for other studies, potential subjects may be prepared to travel great distances. Therefore, even if an investigator is otherwise qualified to perform the study, if sufficient subjects are not located proximate to the investigator's site, it may be more challenging for the investigator to fulfill the subject  
5 recruitment required for the study. By correlating the geographic location of suitable subjects from the subject database and locations having a relatively higher incidence or prevalence of the disease associated with the study (from the TIA database) to the locations of suitable investigators listed in the investigator database, the present invention is able to locate investigators who are not only qualified, but also proximate to large  
10 numbers of subjects, and thus have the greatest likelihood of fulfilling the sponsor's expectations with respect to both enrollment and quality of performance.

Following the review of the search results from steps 806, 807 and 808, the sponsor makes a subjective assessment in step 810 as to the feasibility of the study based on the results obtained from the TIA, subject and investigator databases. In this step, the  
15 sponsor determines whether there is a sufficiently large pool of potential subjects who are close enough geographically to a potential investigator to make the study feasible. If, in step 810, the sponsor concludes that it would not be feasible to recruit sufficient suitable subjects and/or investigators for the study, the sponsor is given an opportunity to revise the subject and investigator criteria entered in step 804 in an effort to arrive at a feasible  
20 study. In accordance with this aspect, the sponsor repeats the process described above using revised subject and investigator criteria until the sponsor finds a study for which subject and investigator recruitment appears feasible.

The sponsor reaches step 811 either as an entry point into the process, or after the sponsor has determined in step 810 that the study is feasible. In step 811, the sponsor

determines whether the sponsor desires to use the investigator database to perform investigator recruitment for the study. If the sponsor wishes to use the investigator database for investigator recruitment, then in step 815, the sponsor begins by entering study parameter information into the system. A screen shot of a web page that may be used for entering this information is shown in Figures 9A and 9B. In this step, the sponsor enters various parameters about the study into the system. Next, in step 816, the sponsor enters investigator search criteria for the study into the system. Such search criteria could include, for example, one or more specialties that would be desirable for an investigator for the study, information about the prescribing behavior of the investigator, the number of studies that the investigator has conducted, the therapeutic area and disease indication associated with clinical studies previously conducted by the investigator, the distance around the investigator site in which subjects participating in the study should be sought, and the geographic area in which the investigator should be located. Figures 10A and 10B are a screen shot of an exemplary web page that may be used by a sponsor to input the investigator search criteria into the system. In step 818, the sponsor is given the ability to weight one or more of the investigator criteria prior to initiating the investigator search.

In step 820, the investigator criteria and any weight applied by the sponsor, are applied to the investigator database in order to identify potential investigators for the clinical study. In one embodiment, results from queries to the TIA and subject databases for the study are also incorporated into the investigator selection process. By correlating the geographic location of suitable subjects from the subject database and locations having a relatively higher incidence or prevalence of the disease associated with the study (from the TIA database) to the locations of suitable investigators listed in the investigator

database, the present invention is able to identify in step 820 investigators who are not only qualified, but also proximate to where potential subjects with the relevant disease live or are willing to travel.

An exemplary web page that shows the results of an investigator search in accordance with the present invention is shown in Figs. 11A and 11B. As shown in that figure, for each investigator identified in the search, the sponsor is shown the name of the investigator, the investigator's specialty, the city/state in which the investigator is located, the number of studies that the investigator has performed, subject demographic information obtained from the TIA database (i.e. the number of persons listed in the TIA database that are within a predetermined distance of the investigator site and who could potentially qualify as subjects for the clinical study), subject demographic information obtained from the subject database (i.e. the number of subjects listed in the subject database that are within a predetermined distance of the investigator site and who could potentially qualify to participate in the clinical study), the drug prescribing behavior of the investigator (e.g., the drug class prescribing decile associated with the investigator). It will be understood by those skilled in the art that other criteria relevant to the investigator could also be shown on this search results screen including for example, the behavior of the investigator with respect to ordering of laboratory tests/procedures.

In step 822, the sponsor selects one or more investigators for the clinical study, and in step 823 begins the process of engaging the investigator(s) for the study. As mentioned above, this process is accomplished using a secure extranet embodied by the professional site. This extranet preferably includes document templates that allow sponsors (and/or investigators) to quickly generate documents relevant to the launch of a clinical study. These documents include for example, an initial questionnaire that a

5 sponsor may send a potential investigator in order to more fully assess whether or not the investigator would be appropriate to conduct the clinical study. Other documents that may need to be in place before the study is started include a confidentiality agreement between the sponsor and investigator, and a synopsis of the study to be completed. These documents are preferably created using standard templates found in the workspace on the professional site associated with each sponsor or investigator. These documents are also preferably exchanged between the sponsor and investigator only within the extranet thereby insuring that confidentiality of such documents is securely maintained and tracked, and allowing separate version control for each of multiple investigators being recruited for the same study. Figures 12 and 13 are screen shots of web pages from the professional site showing use of the extranet for the creation and tracking of documents necessary for the start of a clinical study. The failure to complete or provide any of the documents required to start the study may be fatal to the investigator recruitment process, and may require repetition of the process (from either step 816 or 822) until the investigator recruitment process can be completed.

After step 823, the sponsor decides whether the sponsor is interested in using the subject database to identify potential subjects for the study. If the sponsor is interested in using on-line and/or off-line patient recruitment and retention services, then in step 817 a combination of on-line recruitment and off-line recruitment is used to identify potential subjects for the study. In the on-line recruitment process, the sponsor enters various criteria necessary to identify potential subjects for the study into the system. These criteria include, for example, the inclusion/exclusion criteria of subjects for the study, the therapeutic area and disease indication associated with the clinical area, and/or the distance around the investigator site in which subjects participating in the study should be

found. The subject criteria are then applied to the subject database, in order to identify on-line potential subjects for the study.

Off-line recruitment is used for identification of potential subjects either by itself (step 819) or in combination with on-line recruiting techniques (step 817). Off-line recruiting is how most participants for clinical studies are currently recruited in prior art systems, and this method involves making contact through media with a potential subject in order to attempt to recruit the subject for a given clinical study. In performing off-line recruiting, the sponsor may optionally use results from a search of the TIA database to assist in identifying a geographic area where subjects for study are more likely to be found.

After a potential subject has been identified (step 817 or 819), the process of pre-screening for participation in the study begins (step 824). In this step, subjects identified using on-line and/or off-line recruitment are notified, and asked whether or not they have an interest in participating in the clinical study. In the case of candidates that were identified on-line using the subject database, the subjects are preferably contacted by the means that they identified during their registration on the subject site (e.g., by electronic mail) in order to preliminarily determine whether they have an interest in participating in the clinical study. A screen shot of an exemplary e-mail used for providing such a notification to a potential subject is shown in Fig. 14. The notification could alternatively be provided using telephone, mail, fax or any off-line communication means. If a potential subject responds to a notification by indicating interest in participating in a clinical study, the subject is provided with a formal questionnaire that asks for information specifically relevant to the clinical study. An exemplary study-specific subject questionnaire is shown in reference to Figs. 15A – 15H. In the preferred embodiment, if



in response to the e-mail notification shown in Fig. 14, the subject indicates interest in participating in the clinical study, a study-specific subject questionnaire such as shown in Figs. 15A – 15H is provided to the subject on a secure web page found on the subject site. The subject then uses this secure web page to answer all of the questions in the subject  
5 questionnaire, and to submit such answers for consideration. As mentioned above, irrespective of whether the subject is ultimately selected for participation in the clinical study, these questionnaire answers are stored in the subject database with the consent of the patient, thereby enriching the subject information stored in that database.

Following the pre-screening process described above, a list of pre-screened  
10 subjects who may be eligible to participate in a clinical study is given to the investigator. Next, in step 826, the investigator schedules an appointment with each of the subjects on his or her pre-screened list. The subject gets examined and signs an informed consent before the investigator can enroll the subject in a study. In step 830, allocation numbers for each of the subjects selected by the investigator for the clinical study are provided to  
15 the sponsor. Since the sponsor must be blind to the identities of the subjects participating in the study, the sponsor is provided with only allocation numbers of the subjects, and no identifying information (such as the name or address of such individuals) is provided to the sponsor.

Finally, in step 832, information about each of the subjects participating in the  
20 study is provided electronically from system 100 to an electronic data capture (“EDC”) company. EDCs are typically used during the performance of a study to store and capture data from investigator(s). By electronically providing information about each of the subjects in the study to the EDC prior to start of the clinical study, the present invention facilitates the set-up of the EDC database prior to the start of a clinical study. In one

embodiment, the present invention includes several different data conversion templates, each of which converts subject data (from the subject database) to a format associated with a given EDC, prior to transmission of any subject data to such EDC.

In some embodiments, the inventive system may be linked to the systems of other entities involved in the clinical studies process, thereby creating an automated clinical studies system from compound development through study feasibility and subject/investigator recruitment, study conduct and post-study marketing.

The sponsor may use the inventive system to identify both investigators and subjects, may have engaged an investigator and simply be recruiting subjects, may be looking for an investigator to take over an ongoing study, or may be looking for an investigator who will then recruit subjects.

#### **Specific Investigator Identification Embodiments**

Fig. 16 is a process flow diagram of a method for identifying eligible investigators for a clinical study in accordance with one embodiment of the present invention.

Specifically, at step 1610, information is stored in database 2200 of the inventive system (in particular, the data is stored in table 2252, field 2252a of Fig. 22E) relating to the geographic location of each of a plurality of investigators. At step 1620, an incidence or a prevalence of each of a plurality of disease conditions in a plurality of different geographic locations is stored in the database.

At step 1630 the system queries the database for a selected disease condition associated with the clinical study at issue. The query results in a list of locations wherein there is a relatively greater incidence or prevalence of the selected disease condition. From the result of this query, the system identifies both investigators that may qualify to perform the clinical study based upon the geographic location of the investigator

compared with the query result, as shown at step 1640, and potential registered subjects. Thus, an investigator located where there is a requisite incidence or prevalence of the selected disease condition is potentially eligible.

Fig. 17 is a process flow diagram showing the steps of a method for identifying  
5 eligible investigators for a clinical study in accordance with another embodiment of the present invention. At step 1710, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding the prescription writing history of each of the investigators with respect to a plurality of classes of medications. The prescription writing history  
10 information is provided by a third party.

At step 1720, information is stored in the database that associates each of the plurality of medications discussed above with one or more disease conditions. At step 1730, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in  
15 correlation between the specific disease condition and related prescriptions. At step 1740 the inventive system identifies an investigator based upon the query results and the investigator's prescription writing history. The determination may be based, for example, upon the volume of prescriptions for the medications written by the investigator as compared to the volume of prescriptions for that medication written by other physicians.  
20 The determination may vary depending upon the specific clinical study, and will be known to those skilled in the art and is within the scope of the present invention.

Fig. 18 is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet another embodiment of the present invention. At step 1810, information is stored in the inventive system database

relating to prospective investigators for clinical studies. This information includes information regarding the history of each investigator's request for laboratory procedures (e.g., blood work for subjects, urinalysis, EKG, etc.). Other requests will be known to those skilled in the art and are within the scope of the present invention.

- 5           At step 1820, information is stored in the database that associates each of the laboratory procedure requests discussed above with one or more disease conditions. At step 1830, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related laboratory procedures.
- 10       At step 1840 the inventive system identifies an investigator based upon the query results and the investigator's laboratory procedure requests. The determination may be based upon the fact that the investigator has never requested a certain laboratory procedure, or always prescribes a certain laboratory procedure. The determination may vary depending upon the specific clinical study, and will be known to those skilled in the art and is within
- 15       the scope of the present invention.

Fig. 19 is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study, in accordance with yet a further embodiment of the present invention. With reference to Fig. 19, in step 1910, information regarding a plurality of investigators is stored in a database. Such information includes the history of

20       each investigator's past participation in clinical studies. The history information is stored in a database of the inventive system (shown at table 2220, field 2220A of Fig. 22A). In step 1920, the database is queried using criteria about past clinical study participation. In step 1930, a qualified investigator for a clinical study is identified based on the results of the query regarding past clinical study participation.

Fig. 21A is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study, in accordance with a further embodiment of the present invention. With reference to Fig. 21A, in step 2101, information regarding a plurality of investigators is stored in a database. Such information includes a geographic  
5 location of subjects located near the investigator. In step 2102, the database is queried using criteria about a selected disease condition. In step 2103, a qualified investigator for a clinical study is identified based on the results of the query and the geographic location of the investigator's subjects.

Fig. 21B is a process flow diagram depicting the steps of a method for identifying  
10 eligible investigators for a clinical study in accordance with another embodiment of the present invention. At step 2104, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding the investigator's medical specialty, which can be supplied either by the investigator or a third party, such as a certification board.

At step 2105, information is stored in the database that associates each of the  
15 investigator's specialty with one or more disease conditions. At step 2106, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related specialties. At step 2107 the inventive system  
20 identifies an investigator based upon the query results and the investigator's specialty.

Fig. 21C is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet another embodiment of the present invention. At step 2108, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes

information regarding the experience of an investigator's medical staff, which may include the actual size of the staff, any particular expertise among the staff, etc. Other information about an investigator's staff will be known to those skilled in the art and are within the scope of the present invention. The staff information can be supplied by the  
5 investigators or third parties.

At step 2109, information is stored in the database that associates the experience of the investigator's medical staff discussed above with one or more disease conditions. At step 2109, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in  
10 correspondence between the specific disease condition and related staff experience. At step 2110 the inventive system identifies an investigator based upon the query results and the experience of the investigator's medical staff.

Fig 21D is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with another embodiment of the  
15 present invention. At step 2112, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the number of clinical studies each investigator has performed. This number can be supplied by the investigators or third parties.

At step 2114, the database is queried wherein information representing a selected  
20 disease condition associated with the specific clinical study is used. At step 2115 the inventive system identifies an investigator based upon the query results and the number of investigator clinical studies.

Fig. 21E is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet another embodiment of

the present invention. At step 2116, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes hospitals with which the investigator is affiliated. This information can be supplied by the investigators or third parties.

5           At step 2117, information is stored in the database that associates each of the investigator hospital affiliates with one or more disease conditions. At step 2118, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. At step 2119 the inventive system identifies an investigator based upon the query results and the investigator's hospital  
10 affiliates.

Fig. 21F is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with a further embodiment of the present invention. At step 2120, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes each of  
15 the investigator's hospital affiliates' number of beds, which may include information regarding how many beds are dedicated to ICU, cancer, OBGYN, etc. The information can be supplied by the investigators or third parties.

At step 2121, the number of hospital beds is associated with one or more disease conditions. At step 2122, the database is queried wherein information representing a  
20 selected disease condition associated with the specific clinical study is used. At step 2123 the inventive system identifies an investigator based upon the query results and the number of beds in an investigator's affiliated hospitals.

Fig. 21G is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet a further embodiment of

the present invention. At step 2124, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding each investigator's insurance provider affiliations. The insurance provider affiliation information can be supplied by the investigators or third parties.

5           At step 2125, information is stored in the database that associates each of the insurance providers with one or more disease conditions. At step 2126, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related insurance providers. At step 2127 the inventive  
10   system identifies an investigator based upon the query results and the investigator's insurance provider affiliations.

Fig. 21H is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet a further embodiment of the present invention. At step 2128, information is stored in the inventive system database  
15   relating to prospective investigators for clinical studies. This information includes information regarding each investigator's mandated IRB relationships. For example, an investigator may be affiliated with a local IRB or central IRB. The mandated IRB relationships information can be supplied by the investigators or third parties.

At step 2129, information is stored in the database that associates each of the  
20   investigators with IRBs. At step 2131 the inventive system identifies an investigator based upon the query results and the investigator's mandated IRB relationships.

Fig. 21I is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet a further embodiment of the present invention. At step 2132, information is stored in the inventive system database



relating to prospective investigators for clinical studies, which includes regulatory agency audits that have been performed for each investigator. This information may include audits from the FDA, or other audits that are known to those skilled in the art. The audit information can be supplied by the investigators or third parties.

5           At step 2133, information is stored in the database that associates each of the regulatory audits with one or more disease conditions. At step 2134, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related audits. At step 2135 the inventive system identifies  
10   an investigator based upon the query results and the agency audits of the investigator.

          Fig. 21J is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with an additional embodiment of the present invention. At step 2136, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the investigator's  
15   PRF affiliations. This information can be supplied by the investigators or third parties.

          At step 2137, information is stored in the database that associates each of the investigators with particular PRFs as appropriate. At step 2138, the database is queried. At step 2139 the inventive system identifies an investigator based upon the query results and the investigator's PRF affiliations.

20           Fig. 21K is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet an additional embodiment of the present invention. At step 2140, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding each investigator's medical equipment, such as is the

investigator has a CAT scanner, and EKG machine, etc. The information can be supplied by the investigators or third parties.

At step 2141, information is stored in the database that associates the types of equipment that an investigator has with one or more disease conditions. At step 2142, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related equipment that an investigator has. At step 2143 the inventive system identifies an investigator based upon the query results and the investigator's equipment.

Fig. 21L is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with a further embodiment of the present invention. At step 2143', information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the investigator practice setting, which is where the actual clinical study is conducted, and where a subject would most likely go to participate. This information is provided by the investigator.

At step 2144, information is stored in the database that associates the investigator practice setting with one or more disease conditions. At step 2145, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and related setting information. At step 2146 the inventive system identifies an investigator based upon the query results and the investigator's practice setting.

Fig. 21M is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with another embodiment of the

present invention. At step 2147, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the investigator's city and state. This information is provided by the investigator.

At step 2148, information is stored in the database that associates each of the investigator's city and state. At step 2149, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease condition and the investigator's city and state. At step 2150 the inventive system identifies an investigator based upon the query results and the investigator's city and state.

Fig. 21N is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with another embodiment of the present invention. At step 2151, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the investigator's name. This information is provided by the investigator.

At step 2152, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. At step 2153 the inventive system identifies an investigator based upon the query results and the investigator's name.

Fig. 21O is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with yet another embodiment of the present invention. At step 2154, information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes information regarding the history of each investigator's laboratory results. The laboratory results information can be supplied by the investigators or third parties.

At step 2155, information is stored in the database that associates each of the laboratory results discussed above with one or more disease conditions. At step 2156, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence  
5 between the specific disease condition and related laboratory results. At step 2157 the inventive system identifies an investigator based upon the query results and the investigator's laboratory results. The determination may vary depending upon the specific clinical study, and will be known to those skilled in the art and is within the scope of the present invention.

10 Fig. 21P is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with a further embodiment of the present invention. At step 2158 information is stored in the inventive system database relating to prospective investigators for clinical studies. This information includes, with respect to each hospital with which the investigator is affiliated, the services performed,  
15 which may include information regarding whether the hospital performs transplants, dialysis, burn units, etc. The information can be supplied by the investigators or third parties.

At step 2159, the services performed are associated with one or more disease conditions. At step 2160, the database is queried wherein information representing a  
20 selected disease condition associated with the specific clinical study is used. At step 2161 the inventive system identifies an investigator based upon the query results and the number of beds in an investigator's affiliated hospitals.

Fig. 21Q is a process flow diagram depicting the steps of a method for identifying eligible investigators for a clinical study in accordance with an additional embodiment of

the present invention. At step 2162, information is stored in the inventive system database relating to prospective investigators for clinical studies, which includes the investigator's hospital claim information. This information pertains to claims made by subjects to a hospital, which claims include disease condition information and also are associated with  
5 an investigator. Such information can be supplied by the investigators or third parties.

At step 2163, information is stored in the database that associates each of the claims with one or more disease conditions. At step 2164, the database is queried wherein information representing a selected disease condition associated with the specific clinical study is used. The query will result in correspondence between the specific disease  
10 condition and related claims. At step 2165 the inventive system identifies an investigator based upon the query results and the claims.

The investigator database may also include any combination of, or all of the above information related to the investigator. Moreover, the query of the investigator database may further include search criteria selected from any, and/or all, and all combinations of  
15 the information stored in the database. Therefore, the query may include any permutation of combinations of the information including the investigator's prescription writing history, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to the medical specialty of the investigator,  
20 information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information

corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, and information

5 corresponding to the investigator's name.

### **Investigator Ranking System**

In selecting an investigator for a particular study, in some embodiments, a sponsor may employ an investigator ranking system which is a tool to help predict the success of an investigator in performing clinical studies. In this embodiment, certain fields of the  
10 investigator database (as discussed in more detail below with reference to Fig. 21) are weighted based on one or more algorithms and an investigator is assigned a ranking value. Some of the fields of the investigator database that may be used are as follows: reported study performance by sponsors; reported study performance by third party sources; 1572 counts from the FDA; FDA audit lists; hospital affiliation; mandated IRB relationships;  
15 drug prescribing decile for related classes of drugs; aggregate subject demographics of disease incidence proximate to investigator location; and self-reported data. The weighting algorithm is derived using the investigator's past clinical study experience as a basis. The specific weighting algorithm can be used as a tool to predict performance by an investigator on studies for drugs in a variety of specialties.

20 Thus, for example, in one embodiment, the fields selected for weighting are as follows: investigator experience (namely, the number of 1572s filed in the last five years); the professional certification (namely, if the investigator is board certified, the number 1 is assigned and if not, a zero value is assigned); scientific leadership (namely, the total number of peer-reviewed publications in the past five years); regulatory criteria

(namely, for any FDA audits conducted in the past five years, assigning the number 1 if no warning letter was issued, assigning a zero value if no audits were conducted, and assigning a -1 if a warning letter was issued); and study coordinator criteria (namely, the total number of study coordinators ACRP certified). The value for investigator experience is weighted by multiplying it by 1; the value for professional certification is weighted by multiplying it by 5; the value for the specific leadership is weighted by multiplying it by 5; the value for the regulatory criteria is weighted by multiplying it by 25; and the value of study coordinator criteria is weighted by multiplying it by 5.

In some embodiments, the inventive system refines these rankings by later analysis of clinical study results.

### **Subject Recruitment**

Fig. 20 is a process flow diagram showing the steps of a method for recruiting a person to participate in a clinical study in accordance with one embodiment of the present invention. As shown in step 2010 of Fig. 20, a person is presented with one or more web pages sponsored by the inventive system, as discussed above and shown in Figs. 2A and 2B. The person may be the subject himself or herself or a caregiver of the subject. The caregiver may be either the legal guardian of the subject, or a friend or relative or other interested person. The web page(s) has a registration form that requests a variety of information from the person. For example, the form may ask for the geographic location of the person, which may include a specific city in which the person resides and the distance the person is willing to travel to participate in a clinical study (with reference to Fig. 3). The registration form also may ask for the gender and age of the person, at least one disease condition of interest to the person, a medical history of the person and/or numerous other factors known to those skilled in the art. The form also may include

contact information, such as a relative or friend who may be contacted in an emergency. Other registration information will be known to those skilled in the art and are within the scope of the present invention.

Further, the form may inquire as to consent information about the person. This information includes queries about the person's date of birth. The form may also inquire as to whether the person wishes to receive notice of one or more clinical studies and permission to send the same. The clinical study information sent may be targeted specifically to the person's disease condition of interest, may be targeted to pharmaceutical histories, geographic location, etc.

At step 2020 of Fig. 20, the person, or caregiver, completes the registration form as presented on the web page(s). The data is submitted to the subject database and stored therein as described later with reference to Fig. 24, shown as Tables 2410 and 2420. Once the database is populated with the registration information, the person or caregiver is automatically registered with the inventive system, as shown in step 2030.

Once the person or caregiver is registered, the inventive system evaluates the information provided in the registration form and determines if the person or caregiver should receive notice of a clinical study, as shown in step 2040. For example, the inventive system asks the person or caregiver to confirm that he or she is legally qualified to provide simple consent to add the person's information to the database and to give permission to receive notices about clinical studies. This determination may be based upon information of the person's age, or whether the person or caregiver actually gave permission to receive such notices, for example.

The system also evaluates the information with respect to the person's possible selection for a clinical study. For example, the system queries the database based on: a



disease condition of interest indicated by the subject; the geographic location of the subject; other information from the registration of the subject or a prior questionnaire completed by the subject; and the geographic location of the investigator that has been selected to perform the clinical study. Other determining factors will be known to those skilled in the art and are within the scope of the present invention.

If the system determines that the person does not match the geographic location and disease condition of any currently available clinical studies, the inquiry about the person ends. In some embodiments, the system asks the person if the system may contact the person about future studies that may match the criteria set forth in the registration by the person. If, so, when a new study is entered, the person may show up as a potentially eligible subject, and an e-mail or other notification will be delivered to the person. If, on the other hand, the data regarding the person matches data related to a clinical study, the system provides the person or caregiver with notification of the clinical study, as shown as step 2050. This notification may be by e-mail, telephone or regular mail, as desired by the person, for example with reference to Fig. 3.

Once a person is notified of a clinical study that may be of interest, the system presents to the person a questionnaire that is specifically associated with the clinical study at step 2060. In some embodiments, the person will receive an electronic mail or other notification that a study may match their needs, and the person initiates contact with the system or with a call center to take the particular pre-screening questionnaire. This questionnaire requests information about the person regarding high level inclusion/exclusion criteria. The answers given by the person or caregiver to the questionnaire are securely stored in the subject database of the system (Fig. 24) at step 2070.

As discussed above, this information is evaluated and the person is pre-screened for a clinical study. If the person's responses to the pre-screening indicate that the person may be eligible to participate in the study, the person will be given an investigator name and address and contact information where the subject can schedule an appointment to undergo a more detailed screening process to determine whether the person is qualified to participate. Should the person not be chosen, the information previously stored in the subject database from the questionnaire is evaluated to determine if the person is qualified to participate in a different clinical study than that previously matched, as shown in step 2080. As with the previous determination made, typical queries include whether the person is within a geographic location (as defined by the person or caregiver) of another clinical study and if the person has a disease condition of interest that corresponds with another clinical study. Other determining factors will be known to those skilled in the art and are within the scope of the present invention.

If it is determined that the person is qualified to participate in a different clinical study, the system provides the person with notice of that clinical study, as was discussed earlier. If the subject is eligible for two studies, the subject is presented with them both simultaneously.

### **Push Technology For Enrolling Participants**

As an alternative to a passive method of enrolling investigators, sponsors, and clinical subjects, push technologies can be used to deliver descriptions of the service and to enroll participants. The subject database accommodates this type of data. Using suitable methods of privacy protection, information can be emailed to unregistered individuals to notify them of the potential to participate in an ongoing study. Similarly, location or ease of access may be important in designing or implementing a study. The

GPS functionalities built into wireless phones and other communications devices combined with the ability to transmit information, such as that provided by Bluetooth wireless technology would permit sponsors or investigators to directly contact individuals within particular locations.

5                    **Selection of Subjects Using Genotype and Phenotype Data**

In addition, the present invention permits more efficient use of genotype as well as phenotype data, and other genetic sequencing information, for better selection of candidates for clinical studies. Thus, medical practitioners, including but not limited to doctors, nurses, blood banks, pharmacists, etc., take blood, tissue scrapings or hair  
10 samples for genetic analysis to determine the presence of various alleles and polymorphisms. Such samples are analyzed for the presence of various alleles that might correlate or be associated with various diseases. This polymorphism analysis is greatly improved by such techniques as the DNA chip. Such chips are manufactured by a number of different sources such as Affymetrix, Santa Clara, California.

15            Alleles that are associated with metabolic polymorphisms can also be identified. This is of great importance if differing breakdown rates or even products of the investigational compound affect the drug's safety or efficacy. In this manner, a sponsor can begin clinical studies on a more homogenous population to simplify the complexities of the testing process. Indeed, such a discrete portion of the population can, in some  
20 cases, arguably qualify for special testing parameters, such as that for an Orphan Drug. After approval of the product for such subpopulations, testing is continued to obtain regulatory approval of the product for the population at large.

Many forms of disease appear to be genetically linked including, for example, early onset breast cancer. In early onset breast cancer, the presence of certain gene

sequences such as the BRCA-1 mutation greatly increase the probability that the disease will occur. In many cases, the presence of the BRCA-1 mutation does not lead to the disease, and the disease also can occur when the BRCA-1 mutation is not present. For a product associated with breast cancer, clinical study sponsors may wish to first test their  
5 product on discrete populations – such as those with the BRCA mutation – to determine if such a discrete population reacts differently to a product compared to the population at large. Most importantly, testing such differing populations can lead to greater safety and efficacy in new drug products for the subpopulations tested. Moreover, identification of differences in response is important in discovering improved drugs. Alternately, the  
10 product may be designed only for use by a discrete population, such as that with a particular disease and a particular genotype.

In the alternative, the sponsor might wish to garner a more heterogeneous population for testing. Moreover, as genomic research advances, regulatory agencies might require studies that specifically target a large number of different alleles to obtain  
15 market approval for the entire population.

This ability to pool test subjects, either individually or as parts of large groups such as could be assembled by blood banks and laboratory testing companies, permits easier marketing of genomic information and stimulates research in this area. The site of the present invention has the ability to act as a clearinghouse to match potential sponsors  
20 with groups or individuals that, for example, have particular genotypes and phenotypes. Indeed, as the cost of genomic testing goes down, the invention may be a centralized location that potential clinical subjects may contact not only for participation in studies, but for background genetic tests. As those of ordinary skill in the art will recognize, the present invention may include genetic sequence information in any of the databases

described herein. Moreover, any of the functionality described herein which is based on or operates on disease condition, medical, or treatment information may also be based on or operate on genetic sequence information.

Investigators, persons or other parties supply genetic sequence information for inclusion in the subject database and/or the TIA database along with other suppliers of clinical subjects post the potential clinical subjects that they have identified by location, genetic background at particular genetic loci, family history, lifestyle or any other criteria and then market access to these subjects to potential sponsors. In this way, the invention stimulates the ease of access to unique subject populations.

The invention also permits more efficient marketing of pharmaceutical products and post-marketing studies. The invention collects and pools information regarding the locations of particular doctors as well as their prescription habits. Such information can be used in the design of post-marketing studies as well as determining which doctors would be most easily approached to sell different drug formulations.

#### **Building the Investigator Database**

As described earlier, prospective investigators enter data into the Investigator Questionnaire (Fig. 7 described above) that includes information regarding the investigator's professional background and information about past clinical studies performed by that investigator. In other embodiments, known to those skilled in the art, data relating to the investigator is provided by the investigator not by way of a web site, but orally or by off-line written means.

Specifically focusing on the information regarding past clinical studies, the investigator is asked for data relating to the specific types of clinical studies the investigator performed in the past, the class of drugs that were tested, the protocol

number, what recruiting commitments were made by the investigator in each of the past clinical studies, how successful the investigator was in meeting the recruiting commitments, how many subjects participated in the study, and of those who began the study, how many actually completed the study. This data is stored in the database 2200 as shown in Fig. 22. For example, the investigator may have committed to recruiting 25 subjects over a six-month period of time for a particular clinical study. The database will thus include information about this commitment and results therefrom, *i.e.* was the investigator successful in meeting this commitment, how many subjects actually participated in the study, and of those subjects who began the study, how many actually completed the study (clinically evaluable subjects).

The investigator database also includes information regarding the investigator's publications in the related medical fields, the number of subjects the investigator treats in a given time-frame, any specialties the investigator may have, what board certifications the investigator has, what types of equipment are available to the investigator, affiliated hospitals, the size and expertise of the investigator's staff, etc. Other types of data relating to the investigator will be known to those skilled in the art and are within the scope of the present invention.

Third party information may be used to validate self-reported information submitted by an investigator. Such third party information may include data received from the FDA through the Freedom of Information Act ("FOIA"). In particular, for every clinical study performed in the United States an investigator must submit to the FDA a Form 1572 or appropriate analog. The non-confidential information of Form 1572 can be obtained through FOIA, and includes, for example, the names and addresses of all of the investigators who conducted a particular clinical study. The FDA also performs audits on

clinical studies, which can result in a Form 483. Again, all non-confidential information from the 483 audit can be obtained through FOIA. Validated data also is obtained from various other third parties such as entities that collect performance data as a result of the conduct of their own businesses.

5 Fig. 22A through 22K is an exemplary data structure for implementing an investigator database 2200. For example, table 2210 includes investigator data related to basics such as name, age, address, phone, etc. Table 2220 contains data about a specific study performed by the investigator, Table 2230 relates to the investigator's specialties, and Table 2240 relates to the investigator's subject population. Shown in Figs. 22C and  
10 22E table 2250 contains data about the investigator's staff. Table 2260 of Fig. 22F contains data regarding the investigator's hospital affiliations. It will be understood by those skilled in the art that the investigator database of the present invention could be implemented using many different formats or structures, and that the particular structure shown in Figs. 22A thorough 22K represents one example of such a data structure.

15 **Example: Use of TIA Database To Assist in Investigator and Subject Selection**

Figs. 22L-P depict use of a disease incidence search on a TIA database to assist in performing investigator and subject selection. The example shown relates specifically to use of the invention to perform a study related to the disease of angina. Initially, the TIA database is queried using angina as the query criterion to identify geographic locations  
20 where the incidence of angina is more prevalent. These areas are identified on a national basis in Fig. 22L, and specifically for the Dallas-Fort Worth area in Fig. 22M. It bears noting that, within the Dallas-Forth area, the TIA database has further identified an incidence value for each sub-region of the Dallas-Fort Worth area. Sites of various investigators in Dallas-Fort Worth that are potentially eligible to perform the study are

also shown on Fig. 22M. These investigator sites were found by querying the investigator database as described above. Fig. 22N shows that there are three eligible investigator sites in the Dallas-Fort Worth Area. These three investigator sites are shown as circled stars in Fig. 22N. Of the three eligible investigator sites, one of the investigator sites is located in a sub-region having a higher incidence of angina than is found in the sub-regions of the other two eligible investigators. As shown in Fig. 22O, the investigator located in the sub-region having the highest incidence of angina is next selected to perform the study. Following selection of this investigator for the study, subjects closest to the site of the selected investigator are identified for screening, as shown in Fig. 22P.

#### **Sponsor Data Access Limitations**

A sponsor who has submitted data for inclusion in the investigator database must be afforded appropriate confidentiality protections to ensure their continued competitive advantage. Thus, in one embodiment of the present invention, the inventive system provides limited access views of such data. This method maintains the confidentiality of clinical study information associated with number of clinical study sponsors. In connection with this method, the clinical study information from the sponsors is received and stored in a database. Each sponsor is permitted full access to the clinical study information submitted by that sponsor and only aggregated access to information submitted by other sponsors. The clinical study information includes, in one embodiment, investigator information, sponsor identification, protocol information, drug indication information, drug class information, clinical study enrollment goal information, actual clinical study enrollment information, and clinically evaluable subjects information. In one embodiment, each sponsor is denied access to the protocol information, drug class information and sponsor identification information of other sponsors.



Fig. 23 is a screen shot showing sponsor access limitations to study data. Aggregated data 2302 can be viewed by all sponsors, whereas data 2304 can only be viewed by the sponsor that supplied that data 2304 to the database. Figs. 26A and 26B depicts an exemplary data structure used for implementing the sponsor access limitations discussed above.

### **Multi-Viewer Content Presentation**

The subject site the inventive system includes content such as, e.g. new articles, feature stories, drug listings, expert Q&A transcripts, etc., from multiple different sources for presentation to potential subjects and other persons visiting the subject site. The content as provided by the source is provided using verbiage which is highly technical and sophisticated. However, the content is transformed and presented to visitors of the subject site in a manner which is lay-accessible. Similarly, content which is collected from various sources for presentation on the professional site is transformed and presented in a manner which is appropriate for individuals accessing the professional site, such as investigators and sponsors.

### **Certification of Investigators**

The professional site may include, in some embodiments, a toolkit presented to investigators which includes training materials for investigators, including training regarding appropriate practices for clinical research on humans. Continuing medical education credits may be awarded to investigators completing a specified amount of training.

### **Permission Based Electronic Mail Marketing**

The systems and methods of the present invention can be utilized for the marketing of FDA approved new drugs and devices. Fig. 27 is a flow diagram of a method for

performing permission-based electronic mail marketing to consumers, in accordance with the present invention. In steps 2710-2720, one or more web pages are presented that allow a person to register with the subject database by submitting registration and permission information to the database. The registration information includes name information and contact information and the permission information indicates whether the person wishes to receive notice of one or more clinical studies. In step 2730, the person is automatically registered with the database upon receipt of the registration and permission information. In step 2740, permission is obtained to send marketing information concerning drugs, medical devices or medical therapies to the person. The database is added to in step 2750 by repeating the above steps for a plurality of persons. Next, in step 2760 a list is generated for use in marketing drugs, medical devices and medical therapies to subjects by querying the database using criteria associated with the drugs, medical devices and medical therapies. Optionally, the system also automatically determines, in accordance with the registration and permission information, whether to provide the person with notice of a clinical study associated with a disease condition of interest to the person.

#### **Optimization of Recruiting Methodology**

As the inventive system collects an ever-increasing amount of data regarding clinical investigators (and, in particular, the best performing clinical investigators), highly effective methods of recruiting clinical study subjects, who are clinically evaluable, may be identified by studying the methods employed by the best performing clinical investigators. Thus, the inventive system will allow for the identification of the clinical investigator recruiting techniques that result in the highest enrollment rates and number of clinically evaluable subjects.

Similarly, as the inventive system collects an ever-increasing amount of data regarding clinical subjects (and, in particular, those who become evaluable), highly effective methods of recruiting subjects, who are most likely to become evaluable, may be identified. Thus, the inventive system will allow for the identification of the clinical  
5 subject recruiting techniques that result in the highest enrollment rates and number of clinically evaluable subjects.

### **Remaining Database Structures**

10 Figs. 24A through 24E depict an exemplary data structure for implementing a subject database 2400. Again, it will be understood by those skilled in the art that the subject database of the present invention could be implemented using many different formats or structures, and that the particular structure shown in Figs. 24A through 24E represents one example of such a data structure. In addition to storing information  
15 inputted by the subject as discussed with reference to Figs. 2 through 6, database 2400 may store the criteria used by a potential clinical subject to search for a particular clinical study. The search criteria selected may be used to provide additional insight into the tendencies and/or interests of a potential clinical subject.

Fig. 25 depicts an exemplary data structure for implementing a study database 2500.

20 Again, it will be understood by those skilled in the art that the subject database of the present invention could be implemented using many different formats or structures, and that the particular structure shown in Fig. 25 represents one example of such a data structure.

While the description herein refers to the information existing in multiple  
25 databases, those of ordinary skill in the art will recognize and understand that all such

information could be stored in a single database or n several databases structured differently than those described herein.

It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof.

- 5 It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but is intended to cover modifications within the spirit and scope of the present invention as defined in the appended claims.

What is claimed is:

1. A method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:

(a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database, wherein the registration information includes at least a geographic location of the person, at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies;

(b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information;

(c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person; and

(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice.

2. The method of claim 1, further comprising the steps of:

(e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and

(f) storing answers submitted by the person or caregiver in the database.

3. The method of claim 2, further comprising the step of :

(g) accessing the information stored along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f).

5     4. The method of claim 1, wherein the questionnaire includes criteria specified by a sponsor of the clinical study for determining whether the person is an eligible subject for the given clinical study.

10     5. The method of claim 1, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (d) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site.

15     6. The method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site.

20     7. The method of claim 1, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver.

8. The method of claim 1, wherein the notice provided in step (d) is sent by regular mail to the person or caregiver.

9. The method of claim 1, wherein the notice provided in step (d) is communicated by telephone to the person or caregiver.

10. The method of claim 1, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of the given clinical study.

11. The method of claim 1, wherein in step (c) a determination is made not to provide the person or caregiver with notice of the given clinical study.

10

12. The method of claim 1, wherein in step (a) the registration information includes a user id, a password, electronic mail address or telephone number, zip code, first name or preferred name, gender, date of birth, whether the person is interested in clinical study information, new medical therapies, or participating in clinical studies.

15

13. The method of claim 1, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of an investigator associated with the study.

20 14. The method of claim 2, wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources.

15. The method of claim 1, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database.

5 16. A method for identifying subjects eligible to participate in a clinical study, comprising the steps of:

(a) accessing a computer database that stores information about a plurality of persons;

10 wherein for each of said plurality listed in the database, the database includes a geographic location of the person, an age and a gender of the person, and disease conditions of interest to the person;

(b) submitting a query to the database, wherein the query includes criteria that reflect eligibility characteristics for persons suitable for participation as subjects in the clinical study; and

15 (c) identifying de-identified data records of persons likely to be subjects eligible for the clinical study based on the query.

17. The method of claim 16, further comprising the steps of:

(d) evaluating a feasibility of the clinical study based on the result of step (c);

20 (e) exploring the feasibility of the clinical study by modifying the criteria and repeating steps (b)-(d) using the modified criteria.

18. The method of claim 16 or 17, wherein step (b) includes querying a therapeutic incidence area database.



19. The method of claim 16 or 17, wherein step (b) includes querying an investigator database.

5 20. The method of claim 16 or 17, wherein the accessed information was submitted by e-mail, regular mail, and personally.

21. The method of claim 16 or 17, wherein the database includes a user id, a password, electronic mail address or telephone number, zip code, first name or preferred name,  
10 whether the person is interested in clinical study information, whether the user is interested in new medical therapies, and whether the person is interested in participating in clinical studies.

22. The method of claim 16 or 17, wherein the criteria that reflect eligibility  
15 characteristics include medications taken by the person, the person's geographic location, disease conditions experienced by the person, and a geographic location of an investigator associated with the clinical study.

23. The method of claim 16 or 17, wherein the database is accessed by a user through a  
20 web site, wherein there is a first firewall between the web site and the user and a second firewall between the web site and the database.

24. The method of claim 16 or 17, wherein the database includes genetic sequence information for each of said plurality listed in the database.

25. The method of claim 16 or 17, wherein the criteria that reflect eligibility characteristics include inclusion/exclusion criteria for the clinical study.

5 26. An integrated on-line interactive forum that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subjects, comprising:

(a) an investigator database that contains information suitable for identification of qualified investigators for clinical studies sponsored by the sponsors;

10 (b) a subject database that contains information suitable for identification of eligible subjects for clinical studies sponsored by the sponsors; and

(c) an extranet coupled to the investigator database and the subject database that allows sponsors and investigators to securely exchange documents required to launch a clinical study.

15

27. The forum of claim 26, further comprising one or more web pages that provide information describing clinical studies to potential clinical study subjects and permit potential clinical study subjects to register for inclusion in the subject database.

20 28. The forum of claim 26 or 27, wherein privacy is protected by denying sponsors access to identifying information stored in the subject database.

29. The forum of claim 28, wherein the identifying information is provided to the qualified investigators for potential subjects in a clinical study.

30. The forum of claim 26 or 27, wherein a web server is used for identifying potential subjects for clinical studies.

5 31. The forum of claim 26 or 27, wherein a web server is used for identifying qualified investigators for clinical studies.

32. The forum of claim 26 or 27 further including a therapeutic incidence area database.

10 33. The forum of claim of 27 wherein the extranet and the one or more web pages are accessed using different URLs.

34. The forum of claim 26 further comprising a website coupled to the extranet that includes content available online for training clinical study investigators.

15

35. The forum of claim 27 further comprising a website coupled to the extranet that includes content available from online for training clinical study investigators.

36. The forum of claim 26 further comprising a link from the subject database to an  
20 electronic data capture company.

37. The forum of claim 27 further comprising a link from the subject database to an electronic data capture company.

38. The forum of claim 26 or 27 further comprising a link to the subject database from an electronic medical records company.

39. The forum of claim 26 or 27 further comprising a study listing database.

5

40. A method for identifying a qualified investigator to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores a geographic location of each of a plurality of investigators; wherein the database also stores an incidence or a prevalence of each of a plurality of disease conditions in each of a plurality of different geographic locations;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the clinical study; and wherein the qualified investigator is identified from the database based on the query and in accordance with the incidence or prevalence of the selected disease condition in the geographic location of the qualified investigator.

15

41. A method for identifying a qualified investigator to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores a geographic location of each of a plurality of investigators; wherein the database also stores a geographic location of subjects for the study;

20

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the clinical study; and

wherein the qualified investigator is identified from the database based on the query and in accordance with the geographic location of subjects for the study.

42. The method of claim 41 wherein the database also stores an incidence or a prevalence of each of a plurality of disease conditions in each of a plurality of different geographic locations; and wherein the qualified investigator is identified from the database also based on the incidence or prevalence of the selected disease condition in the geographic location of the qualified investigator.

43. A method for identifying investigators qualified to perform a clinical study,

10 comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to the prescription writing history of the investigator with respect to a plurality of medications; and

wherein the database also stores information that associates each of the medications with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

20 wherein a given investigator is identified from the database based on the query and in accordance with the given investigator's prescription writing history.

44. The method of claim 43 wherein the prescription writing history of the investigator is provided by the investigator to the database.

45. The method of claim 43 wherein the prescription writing history of the investigator is provided by a party other than the investigator to the data.

5 46. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

10 wherein a data record is stored for each investigator listed in the database and includes information corresponding to a history of laboratory procedure requests made by the investigator; and

wherein the database also stores information that associates each of the historical laboratory procedure requests with one or more disease conditions;

15 (b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a given investigator is identified from the database based on the query and in accordance with the given investigator's historical laboratory request information.

47. The method of claim 46 wherein the investigator's historical laboratory procedure results are provided by the investigator to the database.

48. The method of claim 46 wherein the investigator's historical laboratory procedure results are provided by a party other the investigator to the database.

49. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

5 wherein a data record is stored for each investigator listed in the database and includes information corresponding to past participation of the investigator in clinical studies;

(b) submitting a query to the database, wherein the query includes criteria corresponding to past clinical study experience suitable to qualify investigators for  
10 participating in a clinical study; and

(c) identifying qualified investigators from the database based on the query.

50. The method of claim 49 wherein the past participation of the investigator is provided by the investigator to the database.

15

51. The method of claim 49 wherein the past participation of the investigator is provided by a party other the investigator to the database.

52. A method for identifying investigators qualified to perform a clinical study,  
20 comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to a medical specialty of the investigator; and

wherein the database also stores information that associates the medical specialty with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

5        wherein a qualified investigator is identified from the database based on the query and in accordance with the given investigator's medical specialty.

53. The method of claim 52 wherein the investigator's medical specialty information is provided by the investigator to the database.

10

54. The method of claim 52 wherein the investigator's medical specialty is provided by a party other the investigator to the database.

55. A method for identifying investigators qualified to perform a clinical study,  
15        comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to experience of a medical staff of the investigator;

20        and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and



wherein a qualified investigator is identified from the database based on the query and in accordance with the experience of the medical staff of the qualified investigator's medical specialty.

5 56. The method of claim 55 wherein the information regarding experience of the investigator's medical staff information is provided by the investigator to the database.

57. The method of claim 55 wherein the information regarding experience of the investigator's medical staff information is provided by a party other the investigator to the  
10 database.

58. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of  
15 investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to how many clinical studies have been performed by the investigator;

(b) submitting a query to the database, wherein the query includes information  
20 representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with how many clinical studies have been performed by the qualified investigator.

59. The method of claim 58 wherein the information corresponding to how many clinical studies have been performed by the investigator is provided by the investigator to the database.

5 60. The method of claim 59 wherein the information corresponding to how many clinical studies have been performed by the investigator is provided by a party other the investigator to the database.

61. A method for identifying investigators qualified to perform a clinical study,  
10 comprising the steps of:  
    (a) accessing a computer database that stores information on a plurality of investigators;  
        wherein a data record is stored for each investigator listed in the database and includes information corresponding to hospital affiliations of the investigator; and  
15      (b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and  
        wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's hospital affiliations.

20 62. The method of claim 61 wherein the investigator's hospital affiliations information is provided by the investigator to the database.

63. The method of claim 61 wherein the investigator's hospital affiliations is provided by a party other the investigator to the database.

64. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of  
5 investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to a number of beds in hospital affiliations of the investigator; and

(b) submitting a query to the database, wherein the query includes information  
10 representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the number of beds in hospital affiliation of the qualified investigator.

15 65. The method of claim 64 wherein the number of beds in hospital affiliations of the investigator is provided by the investigator to the database.

66. The method of claim 64 wherein the number of beds in hospital affiliations of the investigator is provided by a party other the investigator to the database.

20 67. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to insurance provider affiliations of the investigator; and

(b) submitting a query to the database, wherein the query includes information  
5 representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the insurance provider affiliations of the qualified investigator.

68. The method of claim 67 wherein the insurance provider affiliations of the investigator  
10 is provided by the investigator to the database.

69. The method of claim 67 wherein the insurance provider affiliations of the investigator is provided by a party other the investigator to the database.

15 70. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and  
20 includes information corresponding to mandated IRB relationships of the investigator; and

wherein the database also stores information that associates the mandated IRB relationships with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the mandated IRB relationships of qualified investigator.

71. The method of claim 70 wherein the mandated IRB relationships of the investigator is  
5 provided by the investigator to the database.

72. The method of claim 70 wherein the mandated IRB relationship of the investigator is provided by a party other the investigator to the database.

10 73. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and  
15 includes information corresponding to regulatory agency audits of the investigator; and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the regulatory agency audits information of the qualified  
20 investigator.

74. The method of claim 73 wherein the information corresponding to regulatory agency audits of the investigator is provided by the investigator to the database.

75. The method of claim 73 wherein the information corresponding to regulatory agency audits of the investigator is provided by a party other the investigator to the database.

76. A method for identifying investigators qualified to perform a clinical study,

5 comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to PRF affiliations of the investigator; and

10 wherein the database also stores information that associates the PRF affiliations with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

15 wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's PRF affiliations.

77. The method of claim 76 wherein the investigator's PRF affiliations information is provided by the investigator to the database.

20 78. The method of claim 76 wherein the investigator's PRF affiliation information is provided by a party other the investigator to the database.

79. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to equipment of the investigator; and

5 wherein the database also stores information that associates the equipment of the investigator with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

10 wherein a qualified investigator is identified from the database based on the query and in accordance with the equipment of the qualified investigator.

80. The method of claim 79 wherein the investigator's equipment information is provided by the investigator to the database.

15 81. The method of claim 79 wherein the investigator's equipment information is provided by a party other the investigator to the database.

82. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

20 (a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to the investigator's practice setting; and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's practice setting.

5

83. The method of claim 82 wherein the investigator's practice setting information is provided by the investigator to the database.

84. A method for identifying investigators qualified to perform a clinical study,

10 comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to the investigator's city and state of practice; and

15 wherein the database also stores information that associates the investigator's city and state of practice information with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query

20 and in accordance with the qualified investigator's city and state of practice information.

85. The method of claim 84 wherein the investigator's city and state of practice information is provided by the investigator to the database.



86. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

5 wherein a data record is stored for each investigator listed in the database and includes information corresponding to the investigator's name;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

10 wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's name.

87. The method of claim 86 wherein the investigator's medical specialty information is provided by the investigator to the database.

15 88. The method of claims 43, 44, or 45 wherein the query further includes search criteria selected from the group consisting of, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to the medical specialty of the investigator, information corresponding to experience of a medical staff of the  
20 investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding

to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information  
5 corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

10

89. The method of claims 46, 47, or 48 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to past participation of the investigator in clinical studies, information corresponding to the medical specialty  
15 of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information  
20 corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information

corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information  
5 corresponding to the investigator's name.

90. The method of claims 49, 50, or 51 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of  
10 laboratory requests made by the investigator, information corresponding to the medical specialty of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the  
15 investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice,  
20 investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in

each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

91. The method of claims 52, 53, or 54 wherein the query further includes search criteria  
5 selected from the group consisting of the prescription writing history of the investigator  
with respect to a plurality of medications, information corresponding to a history of  
laboratory requests made by the investigator, information corresponding to past  
participation of the investigator in clinical studies, information corresponding to  
experience of a medical staff of the investigator, information corresponding to how many  
10 clinical studies have been performed by the investigator, information corresponding to  
hospital affiliations of the investigator, information corresponding to insurance provider  
affiliations of the investigator, information corresponding to mandated IRB relationships  
of the investigator, information corresponding to regulatory agency audits of the  
investigator, information corresponding to PRF affiliations of the investigator, information  
15 corresponding to equipment of the investigator, information corresponding to the  
investigator's practice setting, information corresponding to the investigator's city and  
state of practice, investigator information corresponding to services performed at the  
investigator hospital affiliates, information corresponding to investigator laboratory  
results, information corresponding to the geographic location of subjects of the  
20 investigators, information corresponding to the incidence or prevalence of each of a  
plurality of disease conditions in each of a plurality of types at geographic locations, and  
information corresponding to claims and information corresponding to the investigator's  
name.

92. The method of claims 55, 56, or 57 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

93. The method of claims 58, 59, or 60 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of

laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

94. The method of claims 61, 62, or 63 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical

- studies have been performed by the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator,
- 5 information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the
- 10 investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.
- 15 95. The method of claims 64, 65, or 66 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to
- 20 experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships

of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and  
5 state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and  
10 information corresponding to claims and information corresponding to the investigator's name.

96. The method of claims 67, 68, or 69 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator  
15 with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical  
20 studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the



- investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the
- 5 investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.
- 10 97. The method of claims 70, 71, or 72 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to
- 15 experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to regulatory agency audits of
- 20 the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory

results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's  
5 name.

98. The method of claims 73, 74, or 75 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of  
10 laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital  
15 affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and  
20 state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and

information corresponding to claims and information corresponding to the investigator's name.

- 5 99. The method of claims 76, 77, or 78 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

100. The method of claims 79, 80, or 81 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.
101. The method of claims 82 or 83 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of

laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical

5 studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information

10 corresponding to equipment of the investigator, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a

15 plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

102. The method of claims 84 or 85 wherein the query further includes search criteria

20 selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience

of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

15

103. The method of claims 86 or 87 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider

affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's city and state of practice.

104. A method for developing a permission based online database, comprising the steps of:

- 15 (a) presenting one or more web pages that allow a person to register with a database by submitting registration information to the database, wherein the registration information includes name information and contact information and permission information indicating whether the person wishes to receive notice of one or more clinical studies;
- 20 (b) automatically registering the person with the database upon receipt of the registration and permission information;
- (c) obtaining permission from the person to send information regarding drugs, medical devices or medical therapies;
- (d) building the database by repeating steps (a) through (c); and

(e) generating a list for use in marketing drugs, medical devices and medical therapies to persons by querying the database using criteria associated with the drugs, medical devices or medical therapies.

105. The method of claim 104, further comprising the steps of:

5 (f) automatically determining, in accordance with the registration and permission information, whether to provide the person with notice of a clinical study associated with a disease condition of interest to the person;

(g) automatically presenting a questionnaire associated with the given clinical study to the person; and

10 (h) storing answers submitted by the person in the database.

106. The method of claim 104, further comprising the step of sending information to persons on the list regarding a drug, medical device and medical therapy.

15 107. A method of maintaining the confidentiality of clinical study information associated with each of a plurality of clinical study sponsors, comprising the steps of:

(a) receiving said clinical study information from said plurality of clinical study sponsors; and

(b) storing said clinical study information in a database;

20 wherein each sponsor is permitted full access to said clinical study information submitted by that sponsor and only aggregated access to information submitted by other sponsors.

108. The method of claim 107 wherein said clinical study information comprises at least one of investigator information, sponsor identification, protocol information, drug



indication information, drug class information, clinical study enrollment goal information, actual clinical study enrollment information, and clinically evaluable subjects information.

109. The method of claim 108 wherein each sponsor is denied access to said protocol information, said drug class information and said sponsor identification information of  
5 other sponsors.

110. A method for ranking a clinical investigator, comprising the steps of:

(a) selecting at least two ranking criteria from the group consisting of investigator experience, professional certification, scientific leadership, regulatory audits and study coordinator experience; and

10 (b) determining the ranking for the clinical investigator by generating a composite ranking score from the at least two ranking criteria.

111. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of  
15 investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to a history of laboratory results of the investigator; and

wherein the database also stores information that associates each of the laboratory  
20 results with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a given investigator is identified from the database based on the query and in accordance with the given investigator's historical laboratory results information.

112. The method of claim 111 wherein the history of laboratory results of the investigator is provided by the investigator to the database.

5 113. The method of claim 111 wherein the history of laboratory results of the investigator is provided by a party other than the investigator to the database.

114. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

10 (a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to services performed in hospital affiliations of the investigator; and

15 wherein the database also stores information that associates the services performed in hospital affiliations with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

20 wherein a qualified investigator is identified from the database based on the query and in accordance with the services performed in hospital affiliations of the qualified investigator.

115. The method of claim 114 wherein the services performed in hospital affiliations of the investigator is provided by the investigator to the database.

116. The method of claim 114 wherein the services performed in hospital affiliations of the investigator is provided by a party other than the investigator to the database.

5 117. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and  
10 includes information corresponding to claims information of the investigator; and  
wherein the database also stores information that associates the claims information with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

15 wherein a qualified investigator is identified from the database based on the query and in accordance with the claims information.

118. The method of claim 117 wherein the claims information of the investigator is provided by the investigator to the database.

20

119. The method of claim 117 wherein the claims information of the investigator is provided by a party other than the investigator to the database.

120. The method of claim 107 wherein the aggregated access provides a lesser degree of detail of said information.

1/114

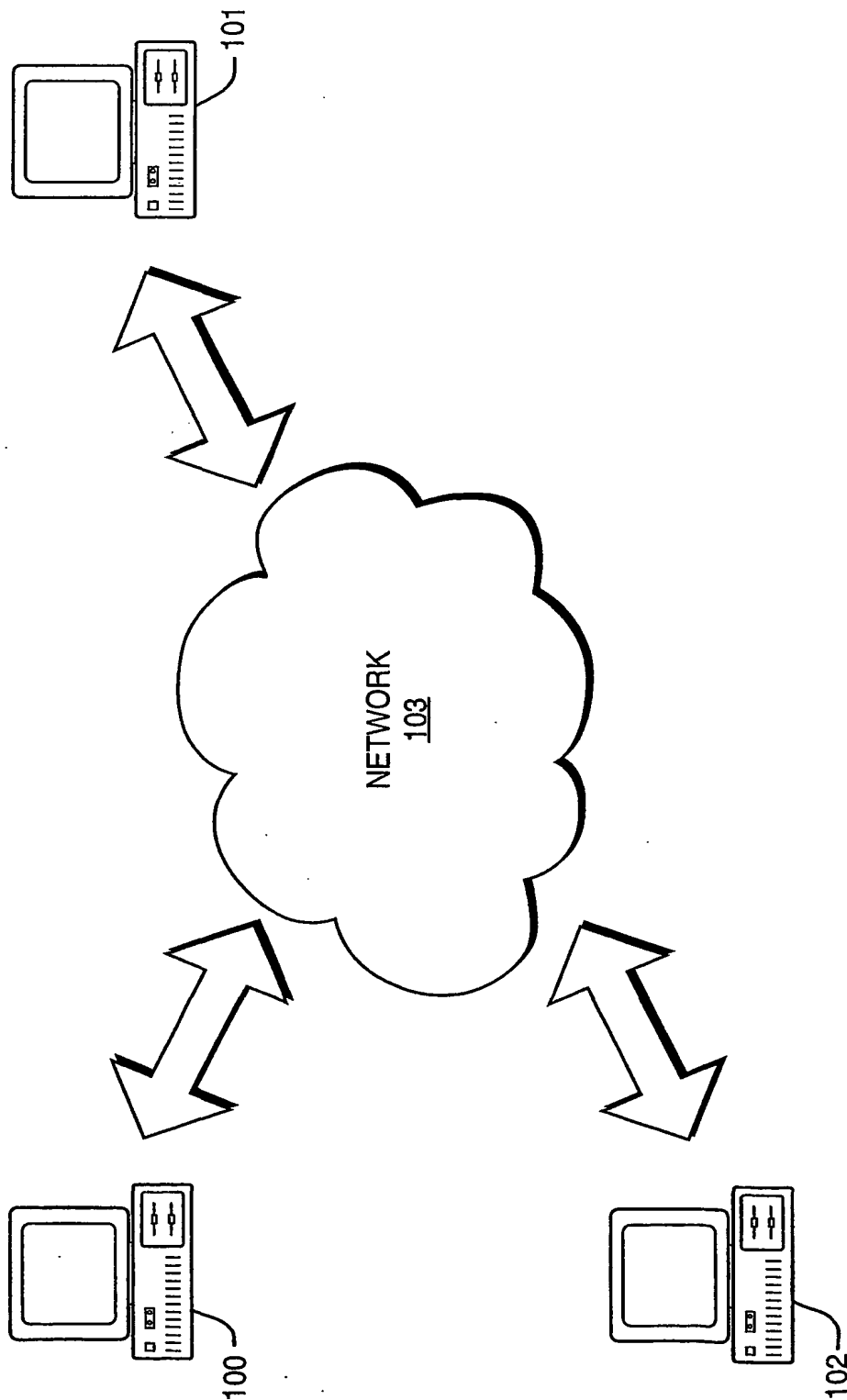
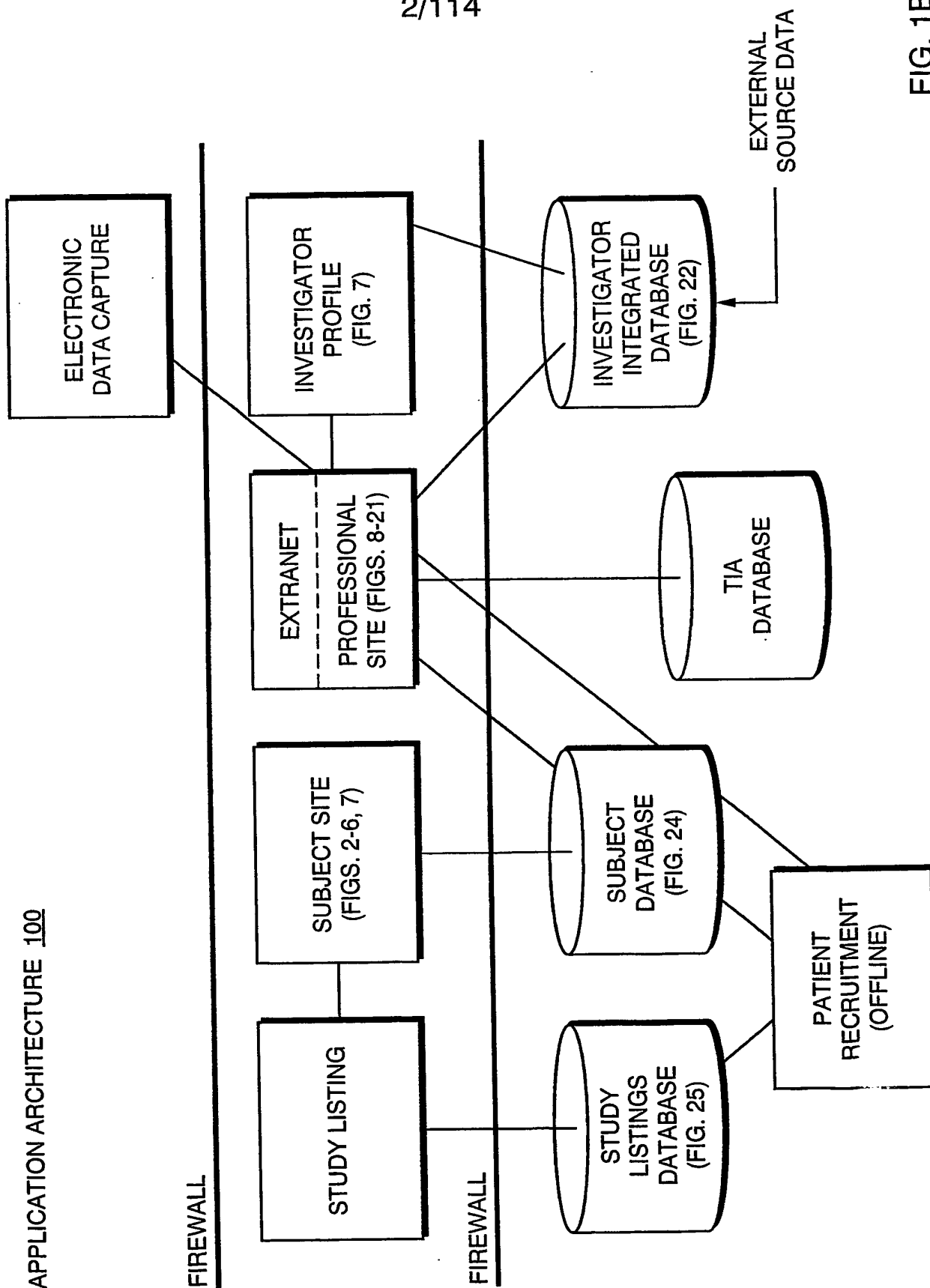


FIG. 1A

2/114



3/114

Search

☐ Feature Stories
 ☐ News Archive
 ☐ Ask the Expert
 ☐ About Clinical Trials
 ☐ Tutorial

Therapeutic Area

☐ Cancer
 ☐ Neurological Conditions

☐ Register Now  
☐ Review Clinical Trials  
☐ Ask Questions and More

200

Register

To register to become a member, just fill in the form below.

201

Email

202

Username

Username 4-digits chars, no blank spaces

203

Password

Password 4-digits chars, case-sensitive

Retype Password

Your privacy is of the utmost concern to us. For more information, read [Privacy & Security Policy.](#)

As part of the registration process and to protect your privacy, we ask that you please choose one of the questions in the box below and type the answer into the second box. If you forget your password, this question will be given to you. After correctly answering the question, you will be asked to reset your password so you can have full access to the site.

Your question

FIG. 2A

4/114

205 Your answer, up to 45 characters.

**Terms of Service**  
Please read the following Terms of Service agreement.

**Terms of Service Agreement**

206 ☐ I Agree ☐ I Do Not Agree

**Benefits of Registration**  
Registered users will benefit from:

- ☐ Our comprehensive clinical trial listings - get trial information and find out how you can be considered for participation in clinical trials.
- ☐ The ability to ask questions of our medical experts.
- ☐ Timely, relevant announcements of new trials and drug information.
- ☐ Exclusive interactive tools, including your own personal library of news information.
- ☐ Emails informing you of updates to our clinical trial listings, news and information, tailored to your selection.
- ☐ A personal profile used to optimize your experience.

FIG. 2B



5/114

Search

☐ Feature Stories  
☐ News Archive  
☐ Ask the Expert  
☐ About Clinical Trials  
☐ Tutorial  

Therapeutic Area

☐ Cancer  
☐ Neurological Conditions  

☐ Register Now  
☐ Review Clinical Trials Ask Questions and More

Search clinical trials

Home /

Personal Information

Personal Information

Medical Condition

Contacts

300

Personal Information

Add or modify your name, password, address and other information about you.

301

First Name

Last Name

Phone #

ext.

Address

City

State

ZIP CODE

Email

302

Gender

☒ Male
 ☐ Female

☐ Change My Password  
☐ Change My Question  
☐ Show My Library welcome page  
☐ Show My Profile welcome page

☒ Yes ☐ No  
☒ Yes ☐ No

☒ Save

FIG. 3

**Search**

---

**Search clinical trials**

[Home /](#)

Personal Information  
 Medical Condition  
 Contacts

## Medical Conditions

Select conditions that interest you and indicate the kind of information you would like to receive. Please select a therapeutic area in the pulldown menu and then click "View" to see the conditions that fall within that area.

If you'd like to see another therapeutic area, simply go to the pulldown menu, make another selection and then click "View". The page will automatically display the new therapeutic area.

**Cancer**

**Cancer**

Please email me updated information on:

Condition	Medical News/Drugs	Clinical Trial Opportunities
Abdominal Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Acute T-Cell Lymphoma	<input type="checkbox"/>	<input type="checkbox"/>
Adrenal Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Bladder Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Bone Marrow Transplant	<input type="checkbox"/>	<input type="checkbox"/>

**Therapeutic Area**

- ☒ Cancer
- ☐ Neurological Conditions

☒ Register Now  
☐ Review Clinical Trials Ask Questions and More

**FIG. 4A**

[illegible]

FIG. 4B

8/114

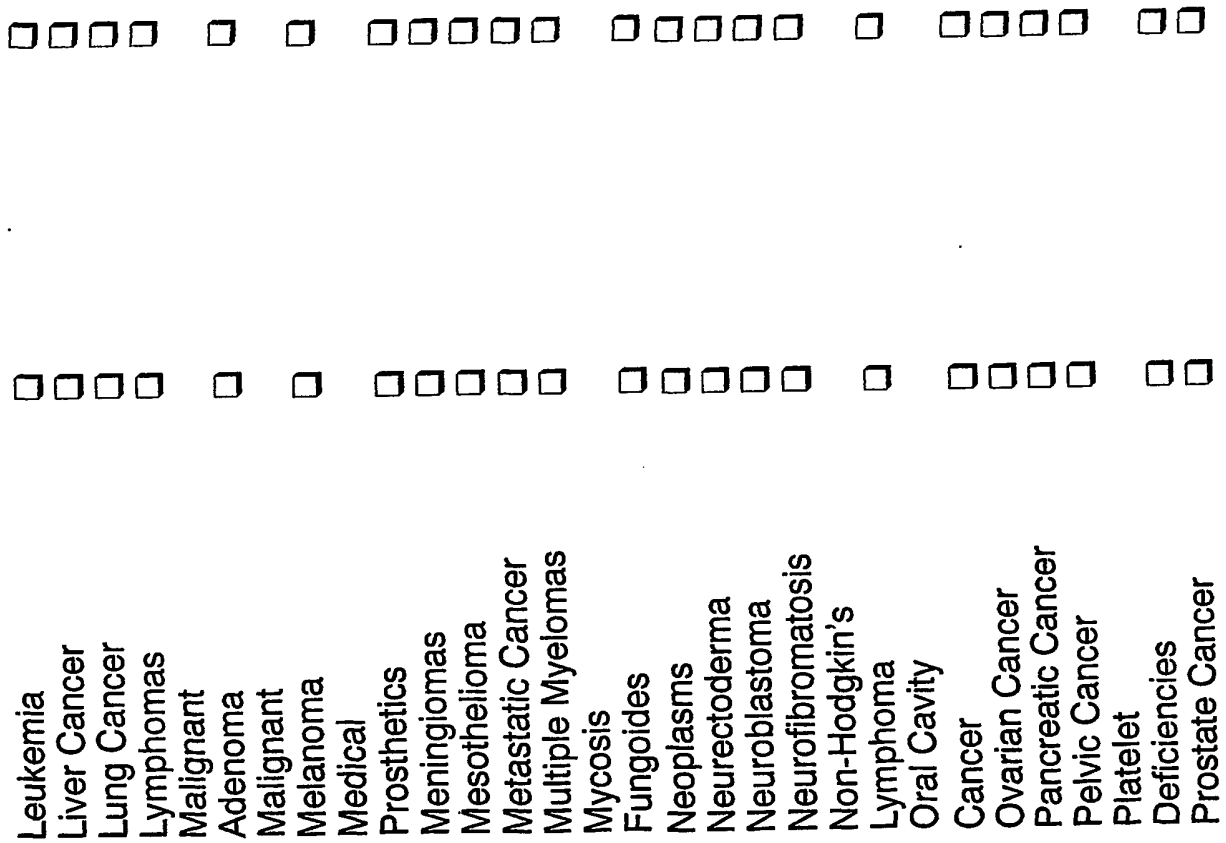


FIG. 4C

Rectal Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Renal Cell	<input type="checkbox"/>	<input type="checkbox"/>
Carcinoma	<input type="checkbox"/>	<input type="checkbox"/>
Sarcoma	<input type="checkbox"/>	<input type="checkbox"/>
Skin Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Spinal Cord	<input type="checkbox"/>	<input type="checkbox"/>
Malignancy	<input type="checkbox"/>	<input type="checkbox"/>
Stomach Cancer	<input type="checkbox"/>	<input type="checkbox"/>
T-Cell Lymphoma	<input type="checkbox"/>	<input type="checkbox"/>
Testicular Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Thrombocytopenia	<input type="checkbox"/>	<input type="checkbox"/>
Thymomas	<input type="checkbox"/>	<input type="checkbox"/>
Vaginal Cancer	<input type="checkbox"/>	<input type="checkbox"/>
Vulvar Carcinoma	<input type="checkbox"/>	<input type="checkbox"/>
Wilms' Tumor	<input type="checkbox"/>	<input type="checkbox"/>

☐ Save

FIG. 4D

10/114

CLINICAL	
<div style="border: 1px solid black; padding: 2px;">           Search <input style="width: 80%;" type="text"/> <span style="float: right;">go</span> </div>	<div style="border: 1px solid black; padding: 2px;">           Search clinical trials <span style="float: right;">▼ go</span> </div>
<a href="#">Home</a> / <a href="#">About Us</a> /	
<h2>About Clinical Trials</h2>	
<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">           Search Clinical Trials         </div> <div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%; padding: 5px;"> <ul style="list-style-type: none"> <li><input type="radio"/> Cancer <sup>502</sup></li> <li><input type="radio"/> Cardiology/Vascular Diseases</li> <li><input type="radio"/> Dental/Maxillofacial Surgery</li> <li><input type="radio"/> Dermatology Plastic Surgery</li> <li><input type="radio"/> Endocrinology</li> <li><input type="radio"/> Gastroenterology</li> <li><input type="radio"/> Hematology</li> <li><input type="radio"/> Immunology/Infectious Diseases</li> <li><input type="radio"/> Musculoskeletal</li> <li><input type="radio"/> Nephrology/Urology</li> </ul> </div> <div style="width: 50%; padding: 5px;"> <ul style="list-style-type: none"> <li><input type="radio"/> Neurological Conditions</li> <li><input type="radio"/> Obstetrics/Gynecology</li> <li><input type="radio"/> Ophthalmology</li> <li><input type="radio"/> Otolaryngology</li> <li><input type="radio"/> Pediatrics/Neonatology</li> <li><input type="radio"/> Pharmacology/Toxicology</li> <li><input type="radio"/> Pulmonary/Respiratory Diseases</li> <li><input type="radio"/> Rheumatology</li> <li><input type="radio"/> Trauma/Emergency Medicine</li> </ul> </div> </div>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">           Clinical Trials FAQ         </div> <ul style="list-style-type: none"> <li><input type="radio"/> Introduction: What are clinical trials ?</li> <li><input type="radio"/> Why are clinical trials important ?</li> <li><input type="radio"/> The clinical trial process.</li> <li><input type="radio"/> How are participant's rights and safety protected during a clinical trial ?</li> <li><input type="radio"/> Who pays for clinical trials ?</li> <li><input type="radio"/> Where can you get more information about clinical trials ?</li> <li><input type="radio"/> Questions you need to ask.</li> <li><input type="radio"/> Common terms used in clinical trials.</li> </ul>
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> Feature Stories         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> News Archive         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> Ask the Expert         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> About Clinical Trials         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> Tutorial         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">           Therapeutic Area         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> Cancer         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> Neurological Conditions         </div> </div> <div style="width: 50%;"> <div style="border: 1px solid black; padding: 5px;"> <input type="radio"/> Register Now Review Clinical Trials Ask Questions and More         </div> </div> </div>	

FIG. 5A

11/114

503

**Introduction: What are clinical trials ?**

Quite simply, a clinical trial is a very carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.

When a promising new medication is identified, the drug undergoes careful evaluation for safety and effectiveness through the clinical trial process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. The pharmaceutical or biotechnology company that is sponsoring the trial reports their findings to the U.S. Food and Drug Administration (FDA). The FDA reviews those findings and if they determine that the drug is both effective and safe to use, then they will make the drug available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

FIG. 5B

12/114

503

If you are looking for clinical trials that may be beneficial for you, please search our clinical trials listing for details on type and location. This is the first step to review the exciting medical research on the potential new treatments of tomorrow that may benefit you today.

© Back to top

### **Why are clinical trials important ?**

Clinical trials are important to increase medical knowledge and find better ways to help people. Generally, the goal of clinical trials is to introduce an investigational treatment that is safer and more effective than the standard treatment for a particular disease or condition. In addition, for those diseases for which there are no treatment options, research and clinical trials may be the only avenue to uncover a potential treatment.

© Back to top

### **The clinical trial process.**

After a drug is successfully tested in laboratory and animal studies, the FDA grants approval for testing to begin in humans. The testing of drugs in clinical trials - also called clinical studies or clinical research - usually occurs in three and sometimes four different phases or steps. Each phase normally involves a larger number of people.

FIG. 5C



13/114

503

**Phase I.** In Phase I trials, researchers study how quickly an investigational treatment works and how the human body processes the investigational treatment. They also try to find dose ranges that will produce the desired effects. Phase I trials typically involve healthy volunteers, but sometimes severely ill patients will participate in these trials.

**Phase II.** In these trials, the safety and effectiveness of an investigational treatment is studied in larger groups of people who have the disease or condition to be treated.

**Phase III.** In Phase III trials, the safety and effectiveness of an investigational treatment are studied in larger populations of people for whom the drug is intended. Typically, there are hundreds or thousands of people in a Phase III trial. Often, the investigational treatment is compared with standard treatments in hopes of finding better ways to help people. The pharmaceutical or biotechnology company that is sponsoring the trial reports the findings from Phase III trials to the U.S. Food and Drug Administration (FDA).

**Phase IV.** Phase IV trials are also called post-marketing trials. Only after the FDA has determined that the medicine is both safe to use and equivalent or superior to existing therapies is it then made available for broader use by physicians and their patients. Phase IV trials take place after a drug has been approved. Findings from Phase IV trials provide additional information about the safety and efficacy of the drug.

© Back to top

FIG. 5D

14/114

503

### **How are participant's rights and safety protected during a clinical trial ?**

The FDA is the government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The rights and safety of people participating in clinical trials are also protected by an Institutional Review Board and by an informed consent form. An Institutional Review Board (IRB) is comprised of both physicians and lay people for the purpose of studying the design of the trial and ensuring that participant's rights are maintained. The informed consent form explains the clinical trial and outlines a participant's rights. You should always be given an informed consent form prior to enrolling in any clinical trial.

© Back to top

### **Who pays for clinical trials ?**

- Sponsors fund clinical trials. This funding can come from the federal government via the National Institutes of Health (NIH) or directly from pharmaceutical and biotech companies.
- The clinical trial sponsor contracts with specialized physicians and/or researchers to administer the trial. Settings for the trials could range from the physician's office to a hospital or research facility. Reimbursement for this service is typically paid out on a per-patient basis.

**FIG. 5E**

503

- Sponsors may pay you to participate in a clinical trial. Typically, these fees, when provided, are nominal.
- Medical care is often provided at no cost to the patients, but they still may be responsible for other expenses such as travel between their homes and the health care facility.

Patients may also have to pay for some medical procedures, tests, or hospital stays if these are considered a part of standard treatment and not part of the clinical trial. Before you enroll, you should determine exactly who pays for what services.

© Back to top

### **Where can you get more information about clinical trials ?**

If you or someone you know has a medical problem and is thinking about taking part in a clinical trial, speak to your health care provider first. In taking an active role in the management of your health, you may want to work closely with your provider to find out if a particular clinical trial is right for you.

© Back to top

16/114

503

**Questions you need to ask.**

- What is the length of your involvement in the clinical trial ? How long will the trial last ?
- Where will you have to go in order to participate in the clinical trial ?
- What are the possible treatments you may receive while in the clinical trial ?
- Do the treatment alternatives they provide cover all possible treatments for this disease ? If not, what are your other treatment alternatives ?
- What procedures are built into the study to keep you safe from harm while you are participating ?
- What are the risks and benefits of participating in the clinical trial ?
- If there are risks, what will happen should you have an adverse reaction to the treatment in the study ?
- What costs may you incur if you participate ?
- Will the treatment be available to you even after the clinical trial has concluded ?
- Where are the funds coming from to conduct this trial ? What is their purpose in sponsoring the trial ?

You should also feel free to ask any other question about the trial you want answered.

© Back to top

17/114

503

**Common terms used in clinical trials.**

**Clinical trial:** A clinical trial - also called a clinical study or clinical research - is a way to evaluate the safety and benefits of a new drug in a carefully controlled setting. The new drug is tested in people who volunteer to participate in the trial.

**Clinical investigator:** A clinical investigator is a doctor or scientist who is responsible for carrying out the planned research activities for a clinical trial. Typically, the doctors chosen for these clinical activities are experts within their medical specialties.

**Coordinator:** A coordinator is a person (usually a nurse or other medical professional) who is responsible for organizing the planned clinical research activities for a trial. The coordinator is also responsible for taking care of important study documents.

**Food and Drug Administration:** The Food and Drug Administration is often referred to as the FDA. The FDA is a government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The FDA also enforces the laws that govern the approval, regulation and monitoring of drugs and medical devices.

FIG. 5H

18/114

503

**Informed Consent:** Informed consent is a process that confirms a patient understands the nature of a study, the risks involved, and the expected benefits of treatment. A written and dated form called the "informed consent form" is signed by a patient to document this process.

**Institutional Review Board:** An Institutional Review Board is usually referred to as the "IRB." The IRB is a group of medical, scientific, and nonscientific people that are responsible for reviewing and approving the planned clinical activities of a study. The group ensures the protection of the rights, safety, and well-being of patients who volunteer for clinical trials.

**Investigational treatment:** Investigational treatment is another term for the drug, treatment, or medical device that is studied in a clinical trial.

**Principal investigator:** The principal investigator is the doctor or researcher who is put in charge of all clinical activities at a particular study location and who supervises the care of patients in the study.

**Protocol:** A protocol is a plan that contains guidelines for a clinical study. The pharmaceutical or biotechnology company that discovered the investigational treatment usually develops the protocol.

FIG. 5I

19/114

503

**Sponsor:** The sponsor is the organization that funds a clinical trial and that develops a plan for the research. The organizations can be a pharmaceutical or biotech company, a research institution, or other health organization.

**Standard treatment:** Standard treatment is a term that refers to approved medical procedures, drugs, tests, or hospitalizations that are a part of the general care considered to be appropriate for certain diseases and conditions. It is the "best treatment" currently known for a given disease. If there are no current treatments shown to be effective against a particular disease, then no treatment would be the standard treatment for that condition.

© Back to top

FIG. 5J

20/114

CLINICAL	
Search <input type="text"/>	<div style="float: right; text-align: right;">go</div> <div style="clear: both;"></div>
<ul style="list-style-type: none"> <li><input type="radio"/> Feature Stories</li> <li><input type="radio"/> News Archive</li> <li><input type="radio"/> Ask the Expert</li> <li><input type="radio"/> About Clinical Trials</li> <li><input type="radio"/> Tutorial</li> <li>Therapeutic Area</li> <li><input type="radio"/> Cancer</li> <li><input type="radio"/> Neurological Conditions</li> </ul>	<div style="text-align: center; margin-bottom: 10px;">             Home / <u>Cancer</u> / go           </div> <h2 style="margin: 0;">Clinical Trials</h2> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <h3 style="margin: 0;">Search Clinical Trials</h3> <p style="margin: 5px 0;">Use these search criteria to find clinical trials.</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">Select a condition</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">and/or</div> <div style="border: 1px solid black; padding: 2px;">Select a state</div> </div> <div style="width: 10%; text-align: center;"> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">▼</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">▼</div> </div> <div style="width: 45%; text-align: right;"> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">602</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">603</div> </div> </div> <div style="text-align: center; margin-top: 10px;"> <span>Ⓞ Contact me for a clinical trial</span> </div> </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <h3 style="margin: 0;">Welcome to Clinical Trials</h3> <p style="margin: 5px 0;">When a promising new medication is identified, careful evaluation of the safety and effectiveness of the drug then occurs in the clinical trials process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. Findings from the clinical trials are reported by the pharmaceutical or biotechnology company that is sponsoring the clinical trial to the US Food and Drug Administration - the FDA. Only after the FDA has determined from reviewing the findings from clinical trials that the medicine is both safe to use and effective is it then</p> </div>

FIG. 6A



21/114

made available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for information on where clinical trials are taking place and the types of trials that are available, you can search our clinical trials listing. If you want to learn more about clinical trials, please see our About Clinical Trials page. These are the first steps in learning about clinical trials and in deciding how medical research on possible treatments for tomorrow may help you today.

About Clinical Trials will provide you with more information.

FIG. 6B

22/114

Search

Go

Search clinical trials

▼

Go

● Feature Stories

● News Archive

● Ask the Expert

● About Clinical Trials

● Tutorial

Therapeutic Area

● Cancer

● Neurological Conditions

General Trial Interest Form

Please select the therapeutic areas and the specific conditions that interest you. Select up to three conditions below. Your selection(s) will be saved to the Medical Conditions section of My Profile, where you can select additional conditions.

Primarily interested

☒ for myself

☐ for someone else

Select therapeutic area

▼

Go

Select therapeutic area

▼

Go

Select therapeutic area

▼

Go

How would you like us to contact you ?

☒ by email

☐ by phone

☐ by regular mail

First Name

Last Name

FIG. 6C

23/114

609

Phone #

ext.

Email

Address

City

State  Select state

ZIP CODE

Best time to contact you  day

Willing to travel  1-10 miles

☐ Submit

☐ Cancel

610 611

FIG. 6D

24/114

<div style="border: 1px solid black; padding: 2px;"> <div style="display: flex; justify-content: space-between; align-items: center;"> <span>Search</span> <span style="border: 1px solid black; padding: 2px 10px;">go</span> </div> <div style="border: 1px solid black; height: 20px; margin-top: 5px;"></div> </div>	<div style="border: 1px solid black; padding: 2px;"> <div style="display: flex; justify-content: space-between; align-items: center;"> <span>Search clinical trials</span> <span style="border: 1px solid black; padding: 2px 10px;">go</span> </div> <div style="border: 1px solid black; height: 20px; margin-top: 5px;"></div> </div>	<div style="text-align: center; border-bottom: 1px solid black; margin-bottom: 10px;"> <b>Step 1 of 3</b> </div> <div style="text-align: center; border-bottom: 1px solid black; margin-bottom: 10px;"> <b>Register</b> </div> <div style="text-align: center;"> <b>Welcome !</b>        To register with _____ we invite you to compute the following questionnaire about you and your health. This should take approximately 5 minutes to complete. _____ will use the information to present you with new medical therapy and clinical trial information that is of specific interest to you.         Your privacy and security are very important to us; therefore we encourage you to review our <a href="#">Privacy &amp; Security Policy</a>.     </div> <div style="text-align: center; border-bottom: 1px solid black; margin-bottom: 10px;"> <b>Choose Your Username and Password</b> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Please choose a username</p> <div style="border: 1px solid black; height: 20px; margin-bottom: 5px;"></div> <p>Please choose a password</p> <div style="border: 1px solid black; height: 20px; margin-bottom: 5px;"></div> <p>Please re-type your password</p> <div style="border: 1px solid black; height: 20px; margin-bottom: 5px;"></div> <p>Choose your reminder question</p> <div style="border: 1px solid black; height: 20px; margin-bottom: 5px;"></div> <p>Please enter your answer to the question</p> <div style="border: 1px solid black; height: 20px; margin-bottom: 5px;"></div> </div> <div style="width: 45%; text-align: center;"> <div style="border: 1px solid black; padding: 2px; display: inline-block;">What is your mother's maiden name ?</div> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">▼</div> </div> </div> <div style="text-align: center; margin-top: 20px;"> <b>Are you seeking information for yourself, or for someone else ?</b>  <div style="display: flex; justify-content: space-around; margin-top: 5px;"> <span><input checked="" type="radio"/> I am seeking information for myself</span> <span><input type="radio"/> I am seeking information for someone else</span> </div> <div style="text-align: right; margin-top: 10px;"> <div style="border: 1px solid black; padding: 5px 15px;">Continue</div> </div> </div>
--	--	--

☐ Feature Articles

☐ Medical News

☐ Ask the Expert

☐ All About Clinical Trials

☐ Tutorial

Therapeutic Area

☐ Cancer

☐ Neurological Conditions

☐ Register Now

Review Clinical Trials Ask Questions and More

FIG. 6E

<div style="border: 1px solid black; padding: 2px;"> Search </div> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> <input type="text"/> </div> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> <input type="button" value="go"/> </div>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <input type="radio"/> Feature Articles  <input type="radio"/> Medical News  <input type="radio"/> Ask the Expert  <input type="radio"/> All About Clinical Trials  <input type="radio"/> Tutorial </div> <div style="text-align: center;"> Therapeutic Area  <input type="radio"/> Cancer  <input type="radio"/> Neurological Conditions </div> </div> <div style="border: 1px solid black; padding: 5px; margin-top: 5px; text-align: center;"> <input type="radio"/> Register Now  Review Clinical Trials Ask Questions and More </div> </div> <div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> Search clinical trials </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> <input type="button" value="go"/> </div> </div> <div style="text-align: center; margin-bottom: 10px;"> <b>Step 2 of 3</b> </div> <div style="text-align: center;"> <b>Personal Information/Medical Conditions</b> </div> <p><i>* denotes required information</i></p> <div style="text-align: center; margin-bottom: 10px;"> <b>Personal Information</b> </div> <div style="margin-bottom: 10px;"> Salutation <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 100px; text-align: center;"> -Pick one- </div> </div> <div> First Name * <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 100px;"></div> </div> </div> <div style="width: 50%;"> <p>(Please enter your first name or the name you prefer to be called when you are welcomed to the site.)</p> <div style="margin-bottom: 10px;"> Last Name <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 100px;"></div> </div> <div style="margin-bottom: 10px;"> Birthdate (month/year)* <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 100px; text-align: center;"> -Pick one- </div> </div> <div style="margin-bottom: 10px;"> Gender* <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 100px; text-align: center;"> -Pick one- </div> </div> <div> Ethnic Background <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 100px; text-align: center;"> -Pick one- </div> </div> </div> </div> <div style="text-align: center; margin-bottom: 10px;"> <b>Contact Information</b> </div> <div> Email Address * <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 150px;"></div> </div> <div style="margin-bottom: 10px;"> Telephone Number <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 50px;"></div> - <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 50px;"></div> - <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 50px;"></div> ext. <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 50px;"></div> </div> <div style="margin-bottom: 10px;"> Postal or Zip Code * <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 100px;"></div> </div> <div> Country <div style="border: 1px solid black; padding: 2px; display: inline-block; width: 100px; text-align: center;"> -Pick one- </div> </div> </div>
---	---

FIG. 6F

26/114

☐ I do not want to receive information by e-mail.

**Medical Conditions**

By completing this section, you will help us to provide you with information that meets your interests.

**I am interested in the following conditions \* (you may choose more than one):**

Medical Conditions: \*

- Acne
- AIDS/HIV
- Allergies
- Alopecia (Hair Loss)

Add >

< Remove

My Conditions:

- Alopecia (Hair Loss)
- Cancer: Prostate
- Seizures (Epilepsy)

Continue

FIG. 6G

27/114

<div>Search</div> <div><input type="text"/> <input type="button" value="go"/></div>		<div>Search clinical trials</div> <div><input type="button" value="go"/></div>	
<div><div><div><input checked="" type="radio"/> Feature Articles</div><div><input checked="" type="radio"/> Medical News</div><div><input checked="" type="radio"/> Ask the Expert</div><div><input checked="" type="radio"/> All About Clinical Trials</div><div><input checked="" type="radio"/> Tutorial</div><div>Therapeutic Area</div><div><div><input checked="" type="radio"/> Cancer</div><div><input checked="" type="radio"/> Neurological Conditions</div></div></div><div><div><input checked="" type="radio"/> Register Now</div><div>Review Clinical Trials Ask Questions and More</div></div></div>		<div><b>Step 3 of 3</b></div> <div><b>Information Request</b></div> <div>I would like to receive information about my conditions:</div> <div><b>Alopecia (Hair Loss):</b><div><input type="checkbox"/> Send me Clinical Trial Opportunities</div><div><input type="checkbox"/> Send me News and New Medical Therapies</div><div><input type="checkbox"/> Do not send me information</div></div> <div><b>Cancer - Prostate:</b><div><input type="checkbox"/> Send me Clinical Trial Opportunities</div><div><input type="checkbox"/> Send me News and New Medical Therapies</div><div><input type="checkbox"/> Do not send me information</div></div> <div><b>Seizures (Epilepsy):</b><div><input type="checkbox"/> Send me Clinical Trial Opportunities</div><div><input type="checkbox"/> Send me News and New Medical Therapies</div><div><input type="checkbox"/> Do not send me information</div></div> <div><b>Terms and Conditions</b></div> <div>Please read the following Terms and Conditions Agreement.</div> <div><div><div>TERMS AND CONDITIONS</div><div>650</div></div></div> <div>By selecting "I Accept", you are accepting the Terms and Conditions above and will become a registered user.</div> <div><div><input type="button" value="I Accept"/></div><div><input type="button" value="I Do Not Accept"/></div></div>	

FIG. 6H

28/114

<div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-between; align-items: center;"> <span>Search</span> <div style="border: 1px solid black; padding: 2px 10px;"> <input type="text" value="Search clinical trials"/> </div> <div style="display: flex; align-items: center;"> </div> </div> </div>	<div style="text-align: center; margin-bottom: 20px;"> <h2 style="margin: 0;">Registration Complete</h2> </div> <p style="text-align: center;">Thank you for registering with us.</p> <p style="text-align: center;">Your request to receive information about the conditions you selected is being processed; you should receive updates periodically.</p> <p style="text-align: center;">As a result of your interest in clinical trial opportunities, we would like to ask you additional questions about your health and medical condition(s). These questions are similar to what a doctor, or other medical professional would ask you when you are being screened for participation in a specific clinical trial. This information is important in determining your possible preliminary eligibility for a specific clinical trial.</p> <p style="text-align: center;">Please take a few more minutes to answer the next set of questions, and keep in mind that these are optional. If you do not have time to complete the additional questions right now, you may update your profile the next time you login to acurian.com. Would you like to continue?</p> <div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="border: 1px solid black; padding: 10px; text-align: center; width: 45%;"> <input type="button" value="Yes, Continue"/> </div> <div style="border: 1px solid black; padding: 10px; text-align: center; width: 45%;"> <input type="button" value="No, Return to Previous Activity"/> </div> </div>
--	--

☐ Feature Articles

☐ Medical News

☐ Ask the Expert

☐ All About Clinical Trials

☐ Tutorial

Therapeutic Area

☐ Cancer

☐ Neurological Conditions

☐ Register Now  
Review Clinical Trials Ask Questions and More

FIG. 6I



**FIG. 6J**

Search

go

Search clinical trials

▼

go

Step 2 of 5

Health Habits (Optional)

It is often important to know your health habits when presenting you with possible clinical trial opportunities.

How often do you exercise ?

- ☐ Never
- ☐ Once a week
- ☐ Twice a week
- ☐ Three times a week
- ☐ Four or more times a week
- ☐ Daily

How often do you visit your primary care physician ?

- ☐ Once a year
- ☐ 2-4 times a year
- ☐ Every month
- ☐ I do not have a primary care physician

Do you smoke cigarettes ?

- ☐ No, I have never smoked
- ☐ No, I quit smoking
- ☐ Yes, daily
- ☐ Yes, occasionally

☐ Feature Articles

☐ Medical News

☐ Ask the Expert

☐ All About Clinical Trials

☐ Tutorial

Therapeutic Area

☐ Cancer

☐ Neurological Conditions

☐ Register Now

Review Clinical Trials Ask Questions and More

FIG. 6K

31/114

If you smoke, how many cigarettes do you smoke per day ?

Please enter:  Cigarettes Per Day

If you smoke, how old were you when you started smoking ?

Please enter:  years old

Do you drink alcoholic beverages ?

- ☐ No
- ☐ Yes, occasionally
- ☐ Yes, 1-2 drinks per day
- ☐ Yes, more than 2 drinks per day

Overall, how would you rate your health ?

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

FIG. 6L

32/114

Search <input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="button" value="Go"/>	Search clinical trials <input style="width: 100%;" type="text"/> <input style="width: 100%;" type="button" value="Go"/>	<h3 style="text-align: center;">Step 3 of 5</h3> <h4 style="text-align: center;">Clinical Trial Experience (Optional)</h4> <p>A clinical trial is a carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.</p> <p>The following questions ask about your experience and interest in participating in clinical trials. These questions are to help us know how many members of ours have participated in clinical trials before.</p> <p>How many clinical trials have you participated in ?</p> <p> <input type="radio"/> 0  <input type="radio"/> 1  <input type="radio"/> 2 - 3  <input type="radio"/> 4 or more         </p> <p>How interested would you be in participating in a clinical trial for a drug that might be used to treat any medical condition(s) you may have ?</p> <p> <input type="radio"/> Very interested  <input type="radio"/> Somewhat interested  <input type="radio"/> Not Sure  <input type="radio"/> Not interested         </p>
---	--	--	---

<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> Feature Articles         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> Medical News         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> Ask the Expert         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> All About Clinical Trials         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> Tutorial         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">           Therapeutic Area         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> Cancer         </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> <input type="radio"/> Neurological Conditions         </div>	<div style="border: 1px solid black; padding: 5px;"> <input type="radio"/> Register Now              Review Clinical Trials Ask Questions and More           </div>
---	---

FIG. 6M

33/114

If interested in clinical trial participation how far would you be willing to travel to participate in a clinical trial ?

- ☐ 1 - 10 miles
- ☐ 11 - 50 miles
- ☐ 51 - 100 miles
- ☐ More than 100 miles
- ☐ Any distance

Save and Continue

Save and Return to Previous Activity

FIG. 6N

34/114

<div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-between;"> <span>Search</span> <span>go</span> </div> <div style="border: 1px solid black; height: 20px; margin-top: 5px;"></div> </div>	<div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-between;"> <span>Search clinical trials</span> <span>go</span> </div> <div style="border: 1px solid black; height: 20px; margin-top: 5px;"></div> </div>	<div style="text-align: center; border-bottom: 1px solid black; padding-bottom: 5px;"> <b>Step 4 of 5</b> </div> <div style="border-bottom: 1px solid black; padding-bottom: 5px;"> <b>Clinical Trial Questions</b> </div> <p>Earlier in the registration process, you expressed interest in clinical trial opportunities. When you are screened for a clinical trial, the doctor at the trial site needs to know more information about your health and the medical condition(s) for which you have been diagnosed. Your answers to the following questions may help determine if you may potentially qualify for a specific clinical trial.</p> <p>Listed below are the conditions you selected earlier in the questionnaire. After you answer questions about each condition, a check mark will appear to the right. Your information will be saved after you complete each section. If you are unable to complete these at this time, we will ask you to update your profile the next time you login to acurian.com.</p> <table style="width: 100%;"> <thead> <tr> <th style="text-align: left;">Condition</th> <th style="text-align: left;">Questionnaire Complete</th> </tr> </thead> <tbody> <tr> <td>Alopecia (Hair Loss)</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Cancer: Prostate</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Seizures (Epilepsy)</td> <td><input type="checkbox"/></td> </tr> </tbody> </table> <div style="text-align: right; margin-top: 20px;"> <div style="border: 1px solid black; padding: 5px; display: inline-block;">Save and Continue</div> <div style="border: 1px solid black; padding: 5px; display: inline-block; margin-left: 20px;">Save and Return to Previous Activity</div> </div>	Condition	Questionnaire Complete	Alopecia (Hair Loss)	<input checked="" type="checkbox"/>	Cancer: Prostate	<input type="checkbox"/>	Seizures (Epilepsy)	<input type="checkbox"/>
Condition	Questionnaire Complete									
Alopecia (Hair Loss)	<input checked="" type="checkbox"/>									
Cancer: Prostate	<input type="checkbox"/>									
Seizures (Epilepsy)	<input type="checkbox"/>									

- ☐ Feature Articles
- ☐ Medical News
- ☐ Ask the Expert
- ☐ All About Clinical Trials
- ☐ Tutorial

Therapeutic Area

- ☐ Cancer
- ☐ Neurological Conditions

☐ Register Now  
 Review Clinical Trials Ask Questions and More

FIG. 60

35/114

<div style="border: 1px solid black; padding: 2px;"> <div style="display: flex; align-items: center;"> <input style="width: 80%;" type="text"/> <input style="width: 20%; text-align: center; border: none; border-bottom: 1px solid black; margin-left: 5px;"/>go         </div> </div>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid black; padding: 2px; flex-grow: 1;"> <div style="display: flex; align-items: center;"> <input style="width: 90%;" type="text"/> <input style="width: 10%; text-align: center; border: none; border-bottom: 1px solid black; margin-left: 5px;"/>go         </div> </div> </div> </div> <div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><b>Search clinical trials</b></p> </div> <div style="width: 50%; text-align: right;"> <input style="width: 100%;" type="button" value="go"/> </div> </div> </div>
<div style="border: 1px solid black; padding: 5px;"> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><b>Feature Articles</b></p> <p><b>Medical News</b></p> <p><b>Ask the Expert</b></p> <p><b>All About Clinical Trials</b></p> <p><b>Tutorial</b></p> </div> <div style="width: 50%;"> <p><b>Therapeutic Area</b></p> <p><b>Cancer</b></p> <p><b>Neurological Conditions</b></p> </div> </div> </div>	<div style="border: 1px solid black; padding: 5px;"> <p><b>Register Now</b> Review Clinical Trials Ask Questions and More</p> </div>
<p><b>Step 5 of 5</b></p> <p><b>Feedback</b></p> <p>Thank you for taking the time to complete your profile.</p> <p>The information you entered will be saved in the <u>My Profile</u> of our site. You may update this information at any time by selecting the <u>My Profile</u> button at the top of the page. We ask that you review your profile at least once a month, so that we may have the most accurate information when trying to present you with clinical trial or medical information.</p> <p>Acurian welcomes your feedback. Please provide us with any comments you would like to share about the questions asked in this registration process.</p> <div style="border: 1px solid black; height: 150px; width: 100%; margin: 10px 0;"></div> <div style="display: flex; justify-content: space-between; width: 100%;"> <div style="width: 45%; text-align: center;"> <input style="width: 100%;" type="button" value="Send to Acurian"/> </div> <div style="width: 45%; text-align: center;"> <input style="width: 100%;" type="button" value="Return to Previous Activity"/> </div> </div>	

FIG. 6P

36/114

<div> <div>Search</div> <div> <input type="text"/> </div> <div> <input type="button" value="go"/> </div> </div>		<div> <div>search clinical trials</div> <div> <input type="button" value="go"/> </div> </div>	
<div> <div> <div> <input type="radio"/> Feature Articles                 <input type="radio"/> Medical News                 <input type="radio"/> Ask the Expert                 <input type="radio"/> All About Clinical Trials                 <input type="radio"/> Tutorial             </div> <div>Therapeutic Area</div> <div> <input type="radio"/> Cancer                 <input type="radio"/> Neurological Conditions             </div> </div> </div>			
<div> <input type="radio"/> Register Now                  Review Clinical Trials Ask Questions and More             </div>			
<div> <div>Thank You</div> <div>                 Your message was sent successfully. Thank you for contacting us. Your comments will help us serve you better.             </div> <div>Return to Previous Activity</div> </div>			

FIG. 6Q



37/114

<div> <div>Search</div> <div> <input type="text"/> <input type="button" value="Go"/> </div> </div>		<div> <div>Search clinical trials</div> <div> <input type="button" value="Go"/> </div> </div>	
<div>Home / <a href="#">Knowledge Center</a> /</div>		<div>612</div>	
<div> <div> <input type="radio"/> Feature Stories           <input type="radio"/> News Archive           <input type="radio"/> Ask the Expert           <input type="radio"/> About Clinical Trials           <input type="radio"/> Tutorial         </div> <div>Therapeutic Area</div> <div> <input type="radio"/> Cancer           <input type="radio"/> Neurological Conditions         </div> </div>		<div> <h2>Welcome to My Library</h2> <p>Here's your chance to create a library of your very own. My Library is where you can store all kinds of information found throughout the site. Whether it's clinical trial information, abstracts on news articles, drug information, perspectives from our medical experts or personal stories, links to the items you select will be saved in this area for as long as you choose to keep them there. All you have to do is click the "Save to My Library" button found throughout the site.</p> <p>In addition, you can type in personal notes along with the items you save. We will not access, use, or review your personal notes for any reason.</p> <p>If you'd like to go directly to one of the five sections, select a link below:</p> <ul style="list-style-type: none"> <li><input type="radio"/> News</li> <li><input type="radio"/> Drug Information</li> <li><input type="radio"/> Clinical Trials</li> <li><input type="radio"/> Ask The Expert</li> <li><input type="radio"/> Feature Stories</li> </ul> <p><input type="checkbox"/> Do not show this page again.</p> </div>	
<div> <input type="radio"/> Register Now           Review Clinical Trials Ask Questions and More         </div>			

FIG. 6R

<p><a href="#">./././ Investigator Questionnaire</a></p> <h2 style="margin: 0;">Investigator Questionnaire</h2> <p>Step 1 of 3</p> <p>Thank you for your interest in joining our investigator data base. The following questionnaire will take approximately one hour to complete. The privacy and security of your information is important to us. All information you submit is transmitted over a secure server.</p> <p>For more information, read our</p> <p>Asterisks (*) denote required fields.</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p><input type="radio"/> Register</p> <hr/> <p><input type="radio"/> Services</p> <hr/> <p><input type="radio"/> FAQ</p> </div>	<div style="text-align: right; margin-bottom: 20px;">  700         </div> <div style="margin-bottom: 20px;"> <div style="display: flex; justify-content: space-between;"> <span>Last Name *</span> <span>701</span> </div> <input style="width: 90%;" type="text"/> </div> <div style="margin-bottom: 20px;"> <div style="display: flex; justify-content: space-between;"> <span>First Name *</span> <span>701</span> </div> <input style="width: 90%;" type="text"/> </div> <div style="margin-bottom: 20px;"> <div style="display: flex; justify-content: space-between;"> <span>Middle Name</span> <span>702</span> </div> <input style="width: 90%;" type="text"/> </div> <div style="margin-bottom: 20px;"> <div style="display: flex; justify-content: space-between;"> <span>Degree(s) *</span> <span>702</span> </div> <input style="width: 90%;" type="text"/> </div> <div style="margin-bottom: 20px;"> <div style="display: flex; justify-content: space-between;"> <span>Primary Research Facility's Organization or Institutional Name *</span> <span>703</span> </div> <input style="width: 90%;" type="text"/> </div> <div style="margin-bottom: 20px;"> <div style="display: flex; justify-content: space-between;"> <span>Street Address *</span> <span>703</span> </div> <input style="width: 90%;" type="text"/> </div> <div style="margin-bottom: 20px;"> <div style="display: flex; justify-content: space-between;"> <span>City *</span> <span>703</span> </div> <input style="width: 90%;" type="text"/> </div> <div style="margin-bottom: 20px;"> <div style="display: flex; justify-content: space-between;"> <span>State/Province/Region*</span> <span>703</span> </div> <div style="display: flex; align-items: center;"> <input style="flex-grow: 1;" type="text"/> <input style="width: 50px; height: 25px; border: 1px solid black;" type="button" value="v"/> </div> </div> <div> <div style="display: flex; justify-content: space-between;"> <span>Country*</span> <span>703</span> </div> <div style="display: flex; align-items: center;"> <input style="flex-grow: 1;" type="text"/> <input style="width: 50px; height: 25px; border: 1px solid black;" type="button" value="v"/> </div> </div>
---	---

FIG. 7A

39/114

Zip Code/Postal Code \*  
 Phone (with area code) \*  
 Telephone Extension  
 Fax (with area code)  
 Email Address

703

Primary Specialty \*  
 Board Certification(s) \*  
 Year of Certification  
 Board Eligible \*  
 Sub Specialty  
 Board Certification(s)  
 Year of Certification  
 Board Eligible  
 Number of years Investigator has participated in trials ? \*

704

-Select One -  
☐ Yes ☐ No  
☐ Yes ☐ No  
☐ Yes ☐ No  
☐ Yes ☐ No  
☐ Yes ☐ No

705

☐ Phase I ☐ Phase II  
☐ Phase III ☐ Phase IV

706

FIG. 7B

40/114

How many Investigators conduct research at this PRF ? \*  Investigators 707

Is the Investigator affiliated with:  
(check all that apply)

☐ Local IRB    ☐ Central IRB  
☐ IEC (Canadian sites only)

If affiliated with a local IRB, what is its name ?

How often does the local IRB meet ?

☐ Weekly    ☐ Bi-weekly  
☐ Monthly    ☐ As needed  
☐ Other

If "other", frequency of local IRB meeting ?

How soon after the IRB meeting will you receive an approval letter ?

---

Has the Investigator ever been audited by the Food & Drug Administration (FDA) or any other regulatory agency ?

709

☐ Yes    ☐ No

FIG. 7C

41/114

<div style="border: 1px solid black; height: 20px; width: 100px;"></div>		<div style="text-align: center;">709</div>	<div style="border: 1px solid black; height: 20px; width: 100px;"></div>		<div style="text-align: center;">710</div>	<div style="border: 1px solid black; height: 20px; width: 100px;"></div>	
<div style="border: 1px solid black; height: 20px; width: 100px;"></div>			<div style="border: 1px solid black; height: 20px; width: 100px;"></div>			<div style="border: 1px solid black; height: 20px; width: 100px;"></div>	
<div style="border: 1px solid black; height: 20px; width: 100px;"></div>			<div style="border: 1px solid black; height: 20px; width: 100px;"></div>			<div style="border: 1px solid black; height: 20px; width: 100px;"></div>	
<div style="border: 1px solid black; height: 20px; width: 100px;"></div>			<div style="border: 1px solid black; height: 20px; width: 100px;"></div>			<div style="border: 1px solid black; height: 20px; width: 100px;"></div>	
<div style="border: 1px solid black; height: 20px; width: 100px;"></div>			<div style="border: 1px solid black; height: 20px; width: 100px;"></div>			<div style="border: 1px solid black; height: 20px; width: 100px;"></div>	
<div style="border: 1px solid black; height: 20px; width: 100px;"></div>			<div style="border: 1px solid black; height: 20px; width: 100px;"></div>			<div style="border: 1px solid black; height: 20px; width: 100px;"></div>	

1. If yes, what was the date of the audit ?

Who was the auditor ?

If audited, was a 483 issued ?

What were the results of the audit ?

2. If yes, what was the date of the audit ?

Who was the auditor ?

If audited, was a 483 issued ?

What were the results of the audit ?

Has the Investigator gone through an audit by a sponsor or CRO ?

1. If yes, what was the date of the audit ?

Who was the auditor ?

FIG. 7D

42/114

710

What were the results of the audit ?

2. If yes, what was the date of the audit ?

Who was the auditor ?

What were the results of the audit ?

Is your PRF

☐ Single specialty  
☐ Multi-specialty

If PRF is multi-specialty, indicate specialties. (one per line)

711

Is your facility part of

☐ Solo practice  
☐ Group practice

Is the facility affiliated with a Site Management Organization (SMO) or research group ?

☐ Yes ☐ No

If affiliated, please specify the SMO name

If affiliated, is this an exclusive relationship ?

☐ Yes ☐ No

© Cancel

© Save and Continue

FIG. 7E

43/114

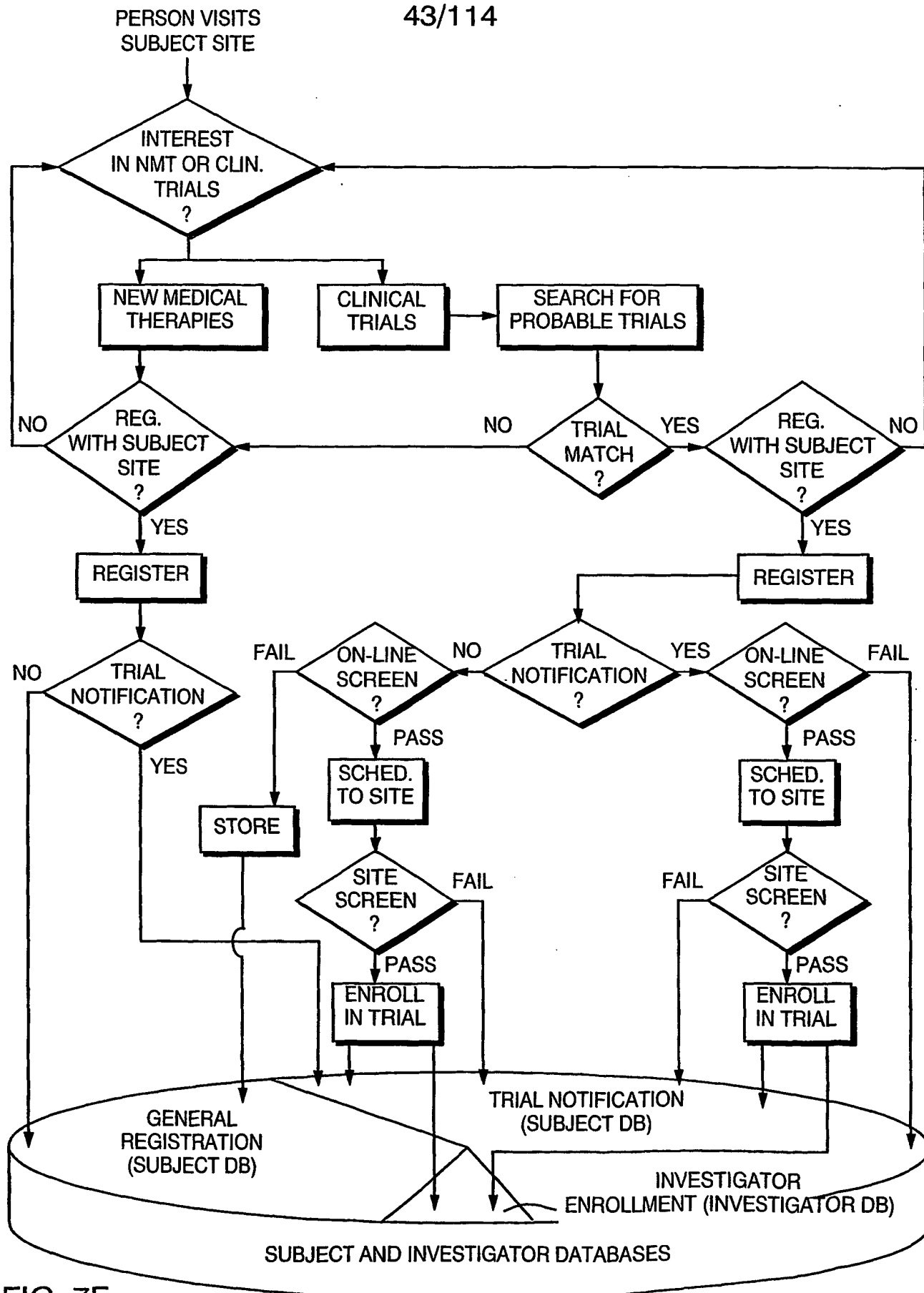


FIG. 7F

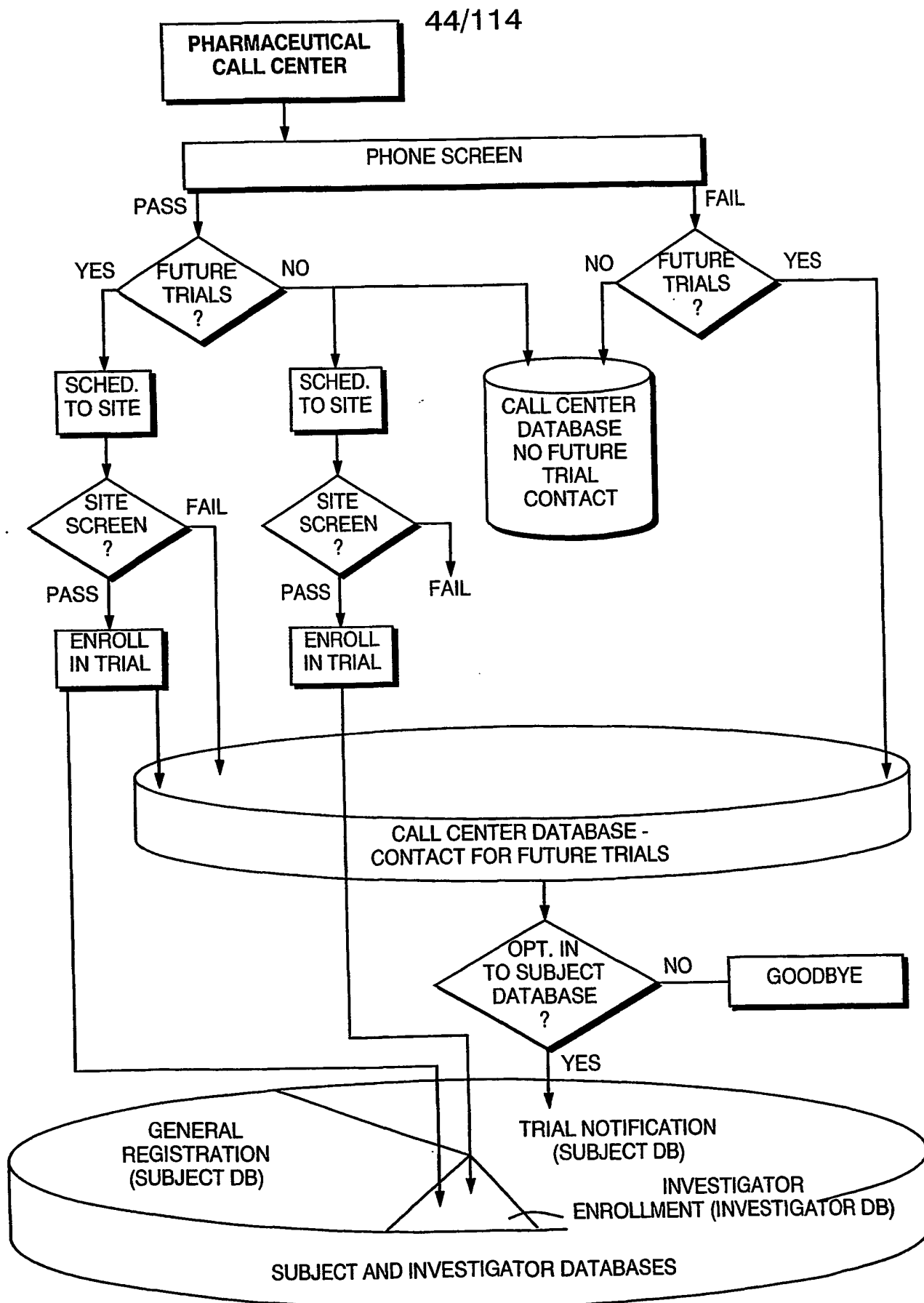


FIG. 7G



45/114

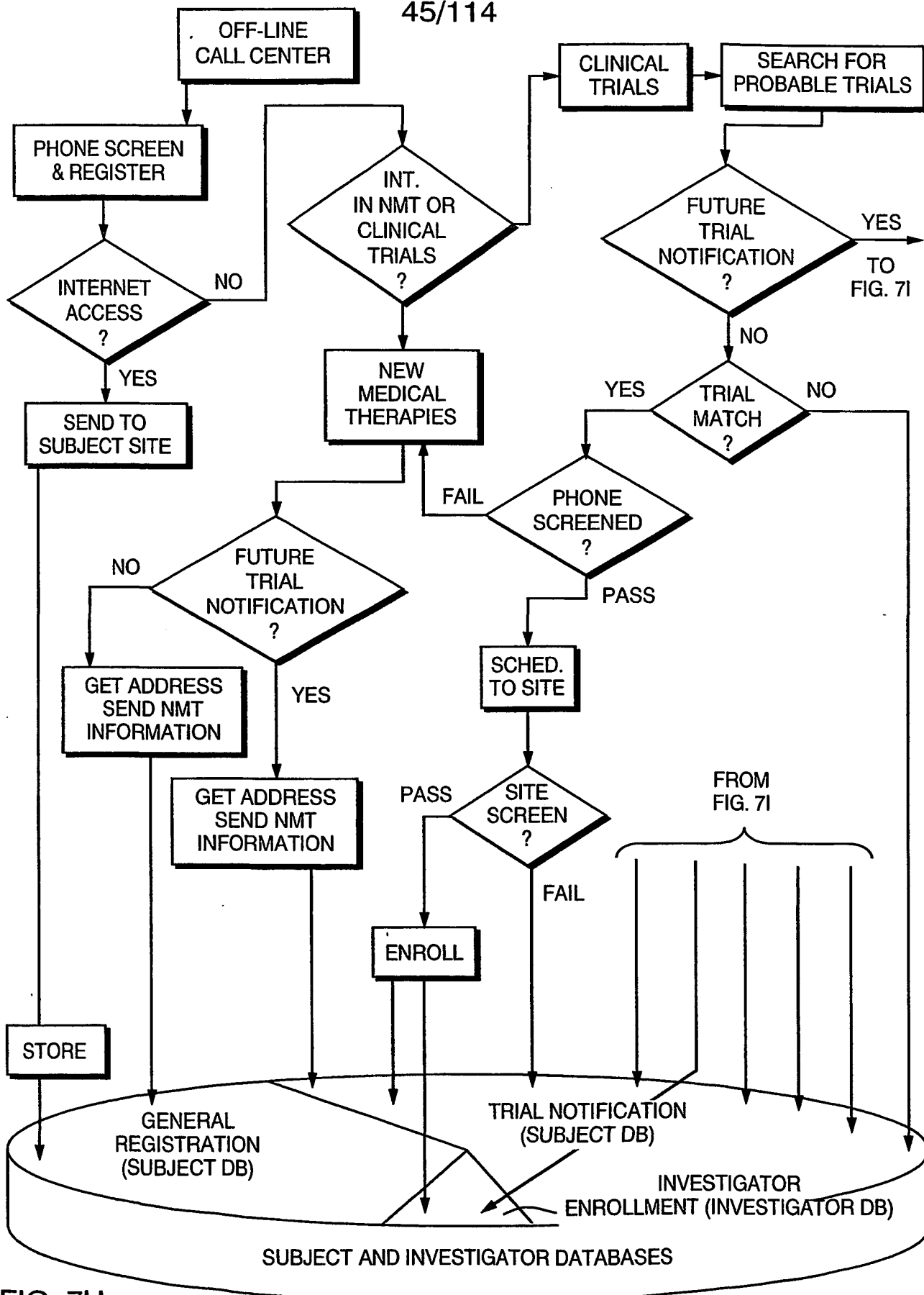


FIG. 7H

46/114

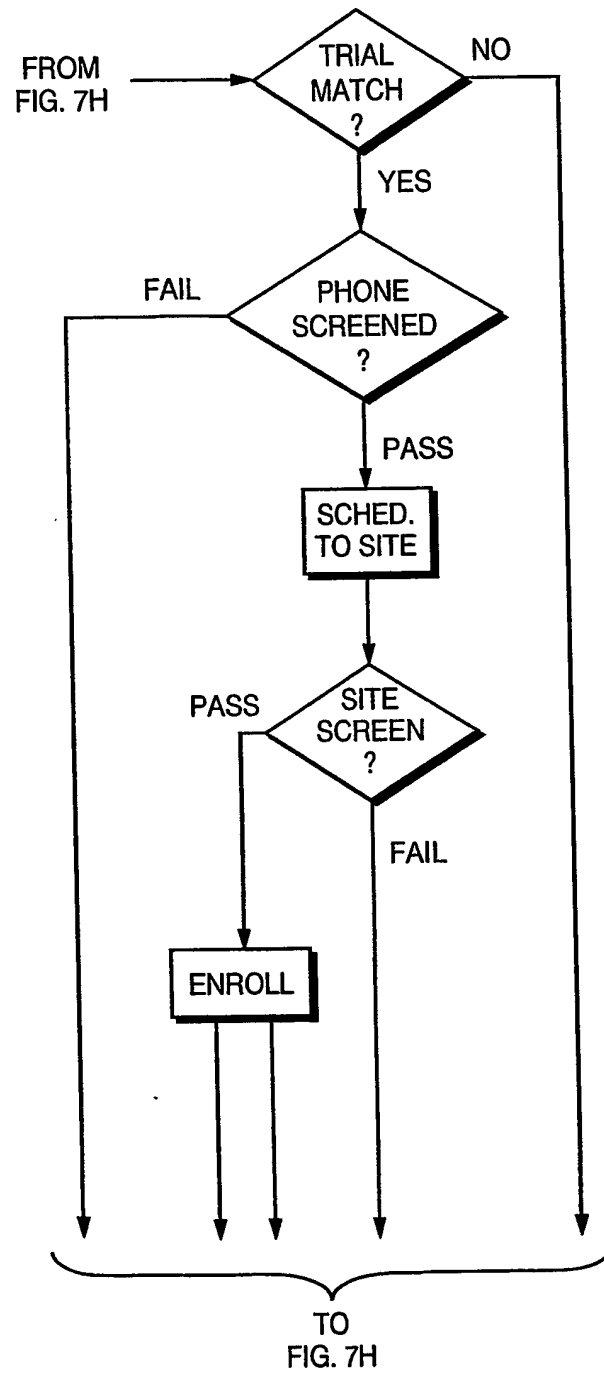


FIG. 7I

47/114

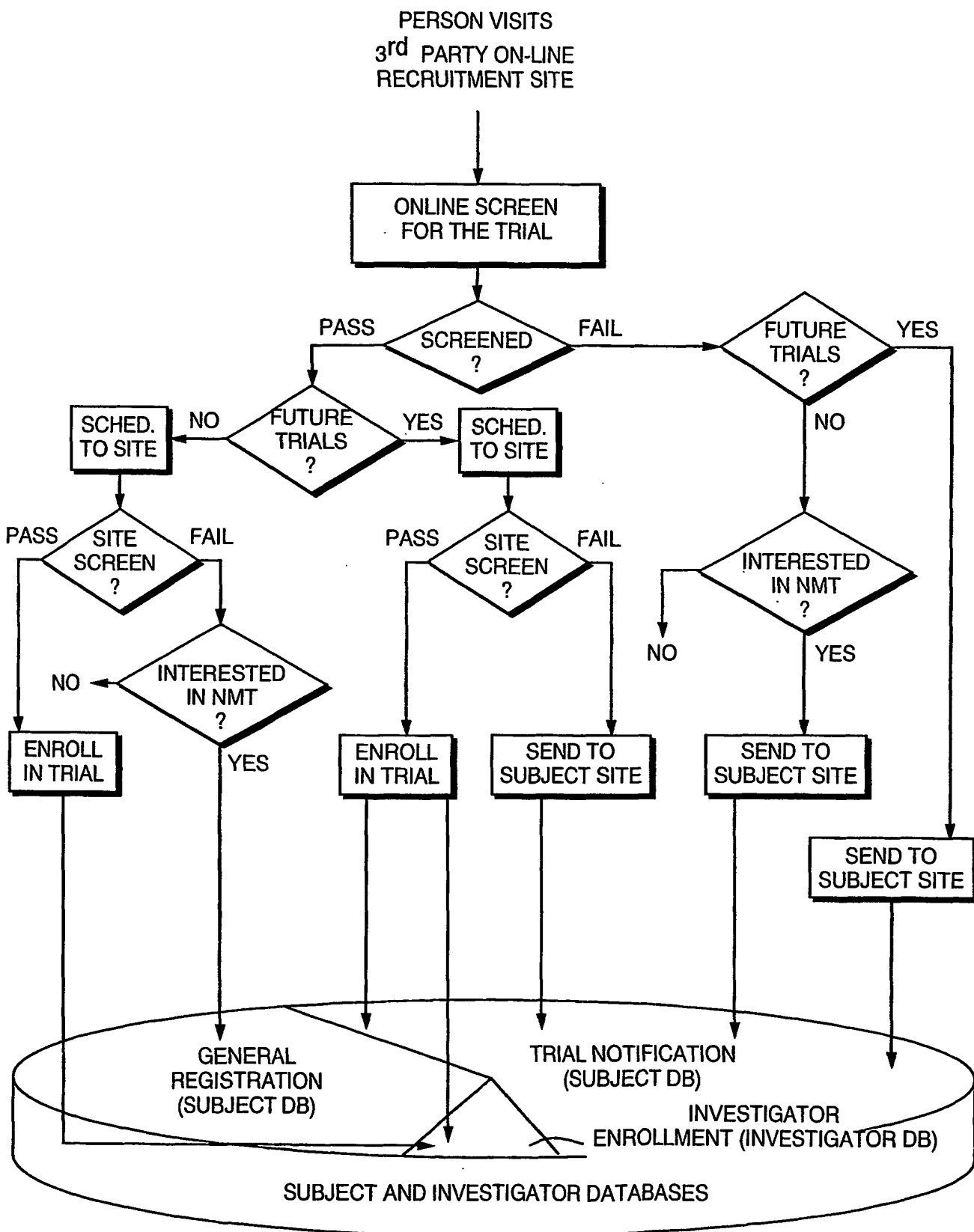


FIG. 7J

SUBSTITUTE SHEET (RULE 26)

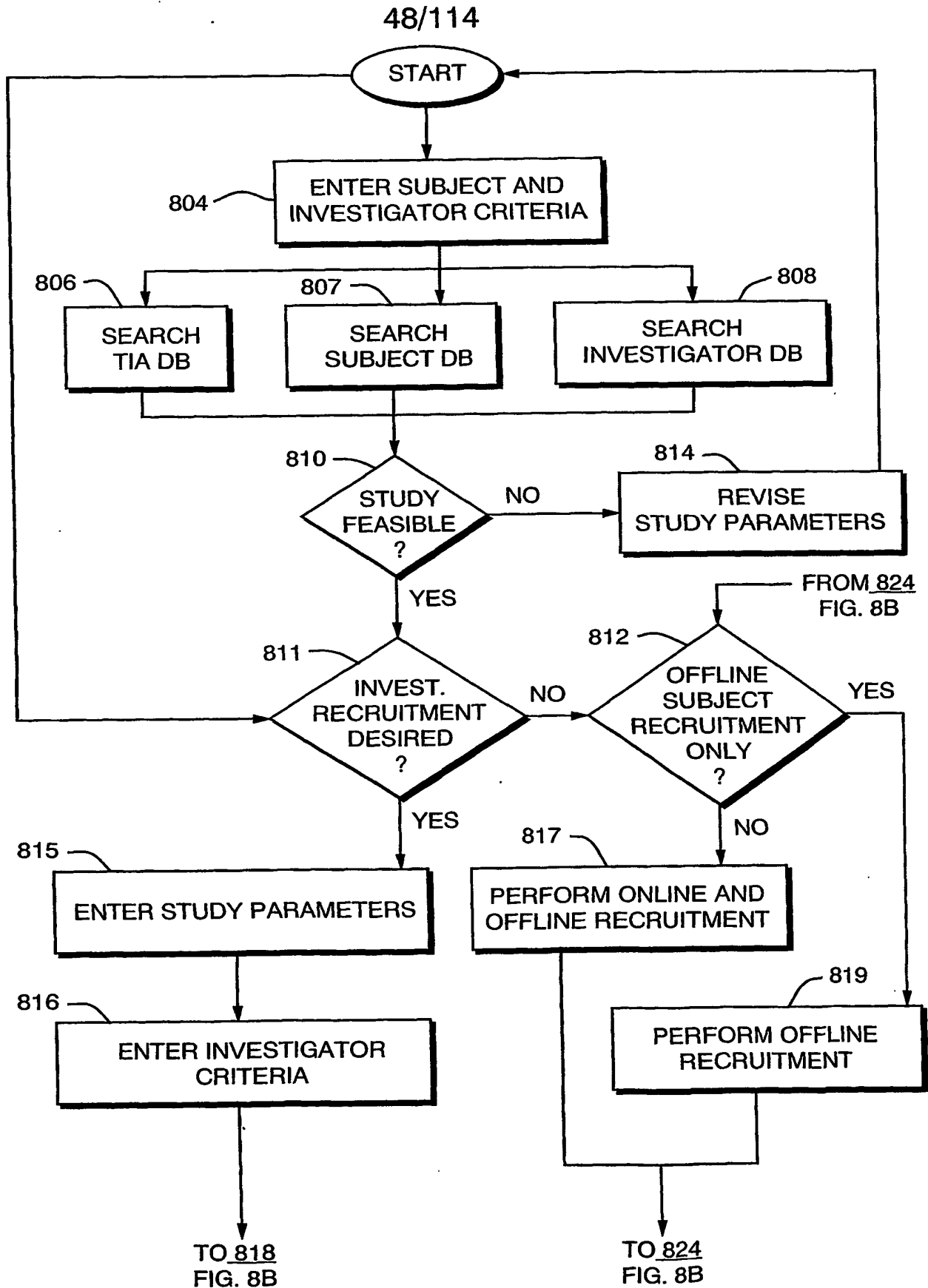


FIG. 8A

SUBSTITUTE SHEET (RULE 26)

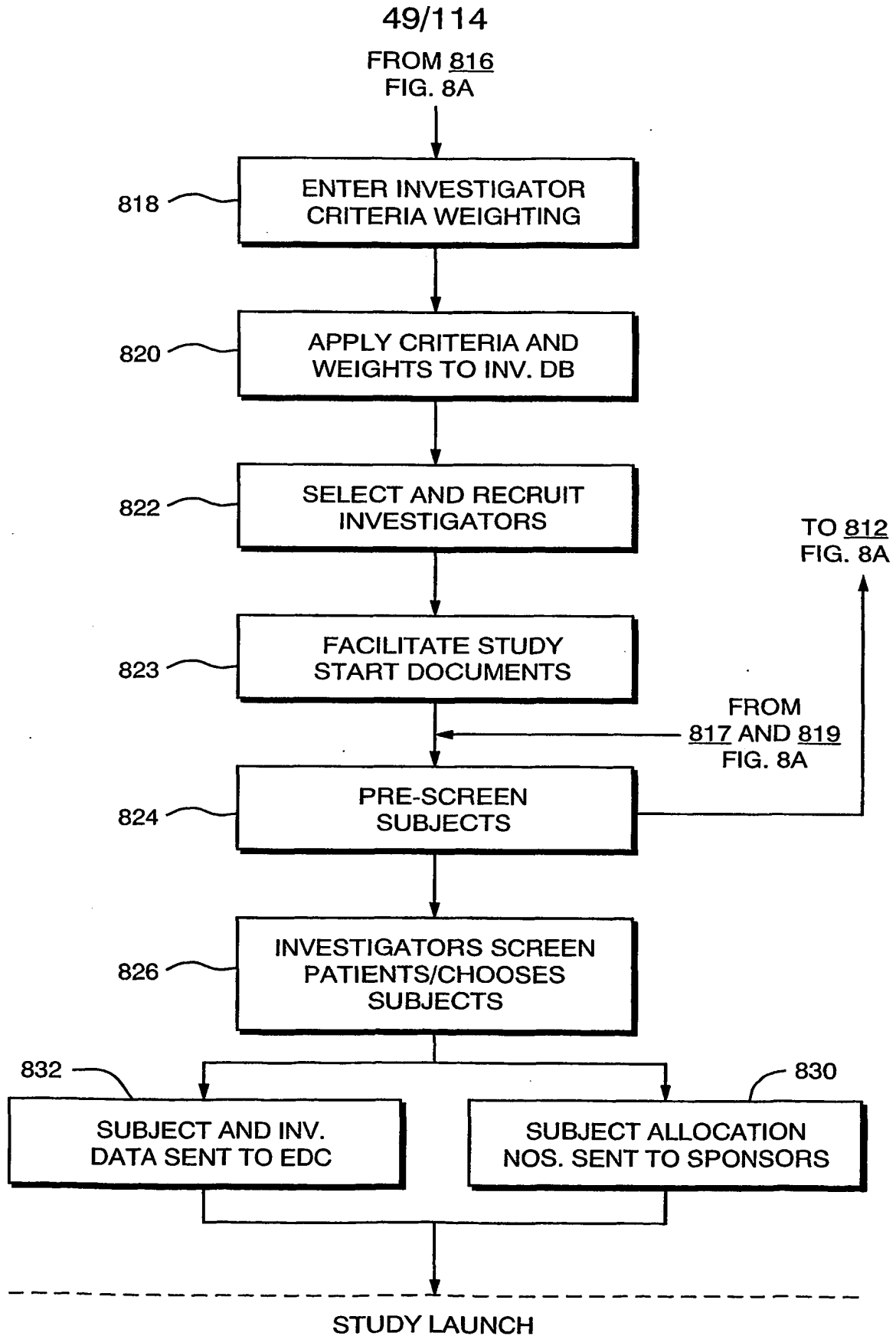


FIG. 8B

SUBSTITUTE SHEET (RULE 26)

Welcome

log out

Register

Services

FAQ

Home

/ Active Trials / Create Trial Parameters

Create Trial Parameters

To create an Active Trials files for a specific protocol please enter or select (from a drop down box) information to create trial parameters.

All fields required

Protocol Number

Protocol Title

Therapeutic Area

Disease Indication

Projected Number of Sites

Projected Number of Patients per Site

Δ

▽

Δ

▽

Δ

▽

-Select a Therapeutic Area -

- Select an Indication -

**FIG. 9A**

51/114

Projected Trial Start Date	<div>January ▾</div> <div>2000 ▾</div>	(Month/Year)
Projected Trial Stop Date	<div>January ▾</div> <div>2000 ▾</div>	(Month/Year)
Projected Enrollment Period (in months)	<div></div>	
Trial Phase	<div>- Select Trial Phase - ▾</div>	

☒ Save Trial

☒ Save and Search for  
Investigators

FIG. 9B

Step 1:

To identify potential investigators - please select a specialty.

Note: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections.

Addiction Psychiatry	Δ
Adolescent Medicine	
Aerospace Medicine	
Allergy & Immunology	▽

Step 2:

To include the prescribing behavior data in the investigator search results class relevant to the therapeutic area and indication. (optional)

Note: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections.

- No Drug Class -	Δ
Acne Therapy	
Aids Therapies	
All Other Misc. Ethical Drugs	▽

Step 3:

To include the number of trials conducted by the investigator in the search, enter a number. (optional)

1	▽
---	---



53/114

**Step 4:**

To access additional databases to enhance the investigator selection process, enter selections below. (optional)

**Patient Therapeutic Area**

**Patient Disease Indication**

**Patient Disease Indication Encounter Category**

Note: To select more than one patient disease encounter category, point to the specialty and press control click. Limit of 2 selections.

- Select a Category -  
Case Load Estimates - Malignancy of hepatobiliary system of pancreas  
Inpatient Discharge Diagnosis - Malignant neoplasm of pancreas

**Patient Distance from Site (in miles)**

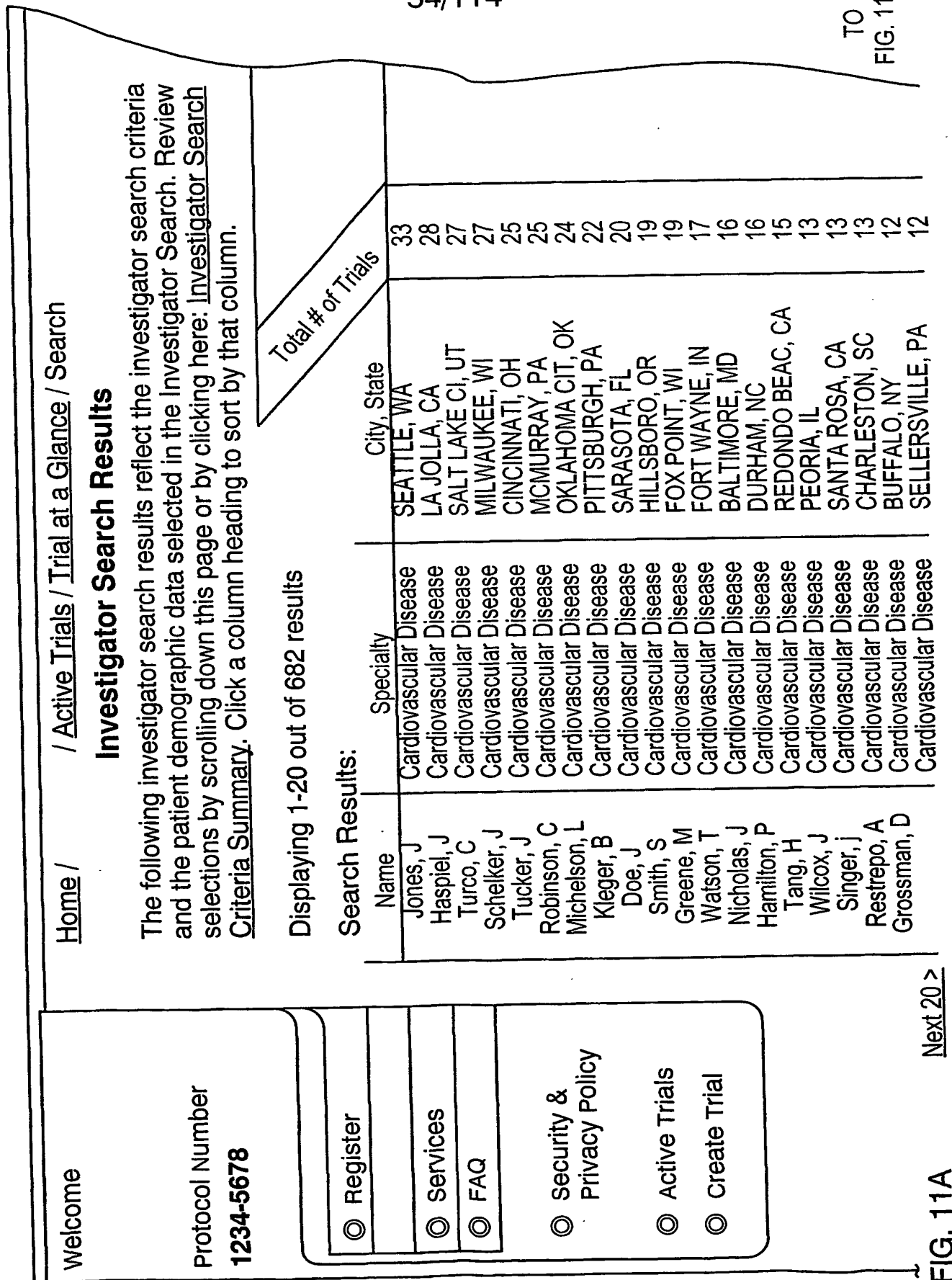
**Step 5:**

To limit search by geographical location - please enter your selections below.

**Municipal Area**

FIG. 10B

54/114

TO  
FIG. 11B

55/114

Patient Demographic Information		Prescribing Decile	Select	Subjects
18-Average Length of Stay - Angin...	1-Anticoagul...	<input type="checkbox"/>	10	
4-Average Length of Stay - Angin...	1-Anticoagul...	<input type="checkbox"/>	20	
5-Average Length of Stay - Angin...	9-Anticoagul...	<input type="checkbox"/>	30	
9-Average Length of Stay - Angin...	1-Anticoagul...	<input type="checkbox"/>	10	
36-Average Length of Stay - Angin...	10-Anticoagul...	<input type="checkbox"/>	20	
6-Average Length of Stay - Angin...	6-Anticoagul...	<input type="checkbox"/>	10	
10-Average Length of Stay - Angin...	3-Anticoagul...	<input type="checkbox"/>	15	
27-Average Length of Stay - Angin...	1-Anticoagul...	<input type="checkbox"/>	12	
7-Average Length of Stay - Angin...	7-Anticoagul...	<input type="checkbox"/>	9	
2-Average Length of Stay - Angin...	3-Anticoagul...	<input type="checkbox"/>	4	
4-Average Length of Stay - Angin...	1-Anticoagul...	<input type="checkbox"/>	12	
2-Average Length of Stay - Angin...	9-Anticoagul...	<input type="checkbox"/>	16	
27-Average Length of Stay - Angin...	6-Anticoagul...	<input type="checkbox"/>	11	
6-Average Length of Stay - Angin...	3-Anticoagul...	<input type="checkbox"/>	22	
10-Average Length of Stay - Angin...	6-Anticoagul...	<input type="checkbox"/>	31	
13-Average Length of Stay - Angin...	5-Anticoagul...	<input type="checkbox"/>	4	
4-Average Length of Stay - Angin...	6-Anticoagul...	<input type="checkbox"/>	1	
5-Average Length of Stay - Angin...	1-Anticoagul...	<input type="checkbox"/>	0	
4-Average Length of Stay - Angin...	5-Anticoagul...	<input type="checkbox"/>	6	
3-Average Length of Stay - Angin...	10-Anticoagul...	<input type="checkbox"/>	1	

FROM  
FIG. 11A

FIG. 11B

Welcome

Protocol Number  
345678

Register

Services

FAQ

Document Summary

Document View

Investigator View

[Home /](#)
[Active Trials /](#)
[Trial at a Glance /](#)

Document Tracking

A multi-center study ... Document Summary

Summary of document status for the selected protocol. Click on any document to go to Document View by Investigator. Click on any investigator to go to specific Investigator Document View. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.

Feasibility

Regulatory

Financial

Vendor Info

CV/Signature

IRB

Misc

Legend

S = Sent

R = Received

C = Completed

Investigator

Smith, J.

Robinson, M.

Questionnaire

Conf. Agreement

Trial Synopsis

Other 1

Other 2

Other 3

Other 4

Other 5

Other 6

Other 7

Investigators:

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Return to Trial at a Glance

SUBSTITUTE SHEET (RULE 26)

BNSDOCID: <WO 0155942A1\_IA>

FIG. 12

57/114

<a href="#">Home</a> / <a href="#">Active Trials</a> / <a href="#">Trial at a Glance</a> / <a href="#">Document Tracking</a> / <a href="#">Document View by Investigator</a>																																				
<h3>Document View by Investigator</h3>																																				
<p>Summary of document status by investigator. Click on any investigator to go to document history of the document selected in the drop down box. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.</p>																																				
<table border="1"> <tr> <td>Feasibility</td> <td>Regulatory</td> <td>Financial</td> <td>Vendor Info</td> <td>CV/Signature</td> <td>IRB</td> <td>Misc</td> </tr> <tr> <td colspan="2">Document: <input type="text" value="Questionnaire"/></td> <td colspan="2"><input type="button" value="▽"/></td> <td colspan="3"><input type="button" value="Create New Document"/></td> </tr> <tr> <td><u>Investigator</u></td> <td><u>Date Sent</u></td> <td><u>Date Rec'd</u></td> <td><u>Date Completed</u></td> <td colspan="3"></td> </tr> <tr> <td>Smith, J.</td> <td>1/27/01</td> <td>1/27/01</td> <td>1/28/01</td> <td colspan="3"></td> </tr> <tr> <td colspan="7">Investigators: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z</td> </tr> </table>		Feasibility	Regulatory	Financial	Vendor Info	CV/Signature	IRB	Misc	Document: <input type="text" value="Questionnaire"/>		<input type="button" value="▽"/>		<input type="button" value="Create New Document"/>			<u>Investigator</u>	<u>Date Sent</u>	<u>Date Rec'd</u>	<u>Date Completed</u>				Smith, J.	1/27/01	1/27/01	1/28/01				Investigators: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z						
Feasibility	Regulatory	Financial	Vendor Info	CV/Signature	IRB	Misc																														
Document: <input type="text" value="Questionnaire"/>		<input type="button" value="▽"/>		<input type="button" value="Create New Document"/>																																
<u>Investigator</u>	<u>Date Sent</u>	<u>Date Rec'd</u>	<u>Date Completed</u>																																	
Smith, J.	1/27/01	1/27/01	1/28/01																																	
Investigators: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z																																				

<p>Welcome</p>	
<p>Protocol Number <b>345678</b></p>	
<p><input type="radio"/> Register</p>	
<p><input type="radio"/> Services</p>	
<p><input type="radio"/> FAQ</p>	
<p><input type="radio"/> Document Summary</p>	
<p><input type="radio"/> Document View</p>	
<p><input type="radio"/> Investigator View</p>	

FIG. 13

58/114

<p>From: Service Provider      Sent: June 6, 2000 To: Ms. Moore Subject: Clinical Trial Opportunity</p>	<p>Dear Ms. Moore:</p> <p>You may qualify for an upcoming clinical trial opportunity. For additional information go to <a href="http://www.website.com/study/zz-234567-22*">http://www.website.com/study/zz-234567-22*</a> and complete the study specific questionnaire.</p> <p>Contact <a href="http://www.service.com">service.com</a> with any questions or comments you may have.</p> <p>Sincerely,</p> <p>Service Provider</p> <p>If you have received this message in error or no longer would like to be considered or contacted about clinical trials please go to <a href="http://www.service.com/remove">http://www.service.com/remove</a></p>
---	---

FIG. 14

59/114

FIG. 15A

### Questionnaire - Alzheimer's

In order to evaluate whether you may be eligible for this study, we will need to review some of your medical history. Are you legally able to provide us with this information for the potential study participant ?

Yes, I am the potential study participant.

Yes, I am a caregiver for the potential study participant with the ability to provide the potential participant's information for the purpose of seeking enrollment in clinical studies.

No, I am not legally able to provide this information.

In answering the following questions, "you" or "your" refers at all times to the potential study participant.

Please provide your gender.

☐ Male

☐ Female

How did you hear about this study ?

☐ Internet

☐ Newspaper Ad

☐ Newspaper Article

☐ Radio Ad

☐ Radio Public Service Announcement

☐ TV Ad

☐ TV program

☐ Physician

☐ Friend

☐ Support Group

☐ Patient Ed Materials

☐ Cardiology Newsletter

☐ Other, please specify: \_\_\_\_\_

60/114

FIG. 15B

The purpose of this medical research study is to evaluate the effect of an investigational drug on the ability to reason, remember, imagine, and learn in humans who have already been diagnosed with mild to moderate probable Alzheimer's Disease. You must live with a caregiver or receive daily visits from a responsible caregiver. The caregiver must be familiar with your recent medical history and be willing to come to 7 doctor visits for a period of 6 months.

After these questions are answered we may be able to refer you to a research site for further screening. After the site reviews your responses to the screening questions, a nurse or other person at the research facility will be calling you. At that time, it will be determined if a first visit should be scheduled to determine whether this study is appropriate for you.

Have you been diagnosed with Alzheimer's disease ?

- ☐ Yes  
☐ No

Have you experienced a deterioration in memory over at least the last 6 months ?

- ☐ Yes  
☐ No

Click the box next to the following if you have experienced a decline in any of the following in at least the last 6 months:

- ☐ orientation  
☐ judgement  
☐ problem solving  
☐ functioning in community affairs  
☐ functioning in home or hobbies  
☐ functioning in personal care



61/114

FIG. 15C

Do you live in a residential home ?

- ☐ Yes  
☐ No

Click the box next to the person who will serve in the role of Caregiver:

I am the Caregiver

Friend

Relative

Paid personnel

No Caregiver

1. Please enter your date of birth:

Day      Month      Year (pull-down boxes)

☐ If female, continue with question 2

☐ If male, continue with question 6

2. Are you/Is (Patient) surgically sterile or post-menopausal for 1 year or more ?

☐ Yes - continue with question #6

☐ No - continue with question #3

3. Do you/Does (Patient) have any other neurological conditions such as:

☐ Parkinson's disease

☐ Pick's disease

☐ Huntingtons chorea

☐ Down's syndrome

☐ Creutzfeldt-Jacob disease

☐ Other \_\_\_\_\_

62/114

4. Do you now or did you at any time, have one or more of the following conditions resulting in your memory or *cognitive* impairment:

- ☐ Major head injury
- ☐ Injury caused by trauma such as boxing
- ☐ Vitamin deficiency
  - ☐ Type (drop down menu)
- ☐ Brain abscess
- ☐ Syphilis
- ☐ Meningitis
- ☐ AIDS
- ☐ Brain cancer
- ☐ Thyroid, parathyroid, or pituitary disease
- ☐ Cushing's syndrome
- ☐ Kidney failure
- ☐ Uncontrolled diabetes
- ☐ Mental retardation

5. Do you have a history of any of the following:

- ☐ Stroke within the past 12 months
- ☐ Epilepsy or convulsions (Childhood convulsions caused by fever continue)
- ☐ Major depression
- ☐ Stomach ulcer that is currently being treated
- ☐ Liver, kidney, or lung disease
- ☐ Kidney stones

6. Have you had a heart attack or coronary artery bypass graft surgery within the past 6 months ?

- ☐ No
- ☐ Yes

FIG. 15D

63/114

7. Do you experience angina (chest pain) that required a change in medication in the past 3 months ?  
☐ Yes  
☐ No
8. Has a doctor told you that you have a heart rate that is slow or less than 50 beats per minute ?  
☐ Yes  
☐ No
9. Do you take medication for high blood pressure or chronic low blood pressure ?  
☐ Yes ☐ Medication(s) taken: (drop down menu)  
☐ No  
☐ Don't know
10. Do you take any medications for the purpose of treating memory loss such as dementia ?  
☐ Yes  
☐ No
11. Are you allergic to any medications ?  
☐ Yes ☐ Which Medication(s) (drop down menu)  
☐ No

FIG. 15E

64/114

12. Are you taking any other medications including vitamins or herbal supplements such as Ginkgo Biloba ?
- ☐ Yes  
☐ Which Medication(s) (drop down menu)  
☐ No
13. Have you ever been enrolled in a research study for galantamine ?
- ☐ Yes  
☐ No  
☐ Don't know
14. Have you taken an investigational drug in the past 30 days or are you taking one now ?
- ☐ No, I have not taken an investigational drug in the past 30 days  
☐ Yes, I have taken an investigational drug in the past 30 days  
☐ Yes, I am taking an investigational drug now
15. How many drinks do you consume in a typical 24-hour period ?
- ☐ 1-2 drinks  
☐ 3-5 drinks  
☐ 6-8 drinks  
☐ more than 8 drinks
16. Have you/patient had a CT scan or MRI of the head during the last 12 months ?
- ☐ Yes  
☐ No

FIG. 15F

65/114

## Questionnaire - Alzheimer's

## SCREEN #2: PATIENT NOT ELIGIBLE FOR STUDY

We appreciate your interest in this study. Unfortunately, from the information you have provided, you are not a candidate for participation in this study. May we have your permission to contact you in the future with information about this or other studies ?

- ☐ Yes, contact me.
- ☐ No, I do not want to be contacted.

FIG. 15G

66/114

## Questionnaire - Alzheimer's

## SCREEN #3: PATIENT POTENTIALLY ELIGIBLE FOR STUDY:

Based on your responses, you may be eligible for the clinical study. We will forward this information to the research site you selected. The research site will contact you shortly to ask you further questions about your health, and possibly to schedule an appointment for the first visit. In the meantime, we will send you a Welcome Kit that contains information about the study. If the site does not contact you within 5-7 business days, please feel free to call the number that will be included in your mailed materials.

In the event that you do not participate in this particular study, may we have your permission to contact you in the future about other studies ?

- ☐ Yes, contact me  
☐ No, I do not want to be contacted

FIG. 15H

67/114

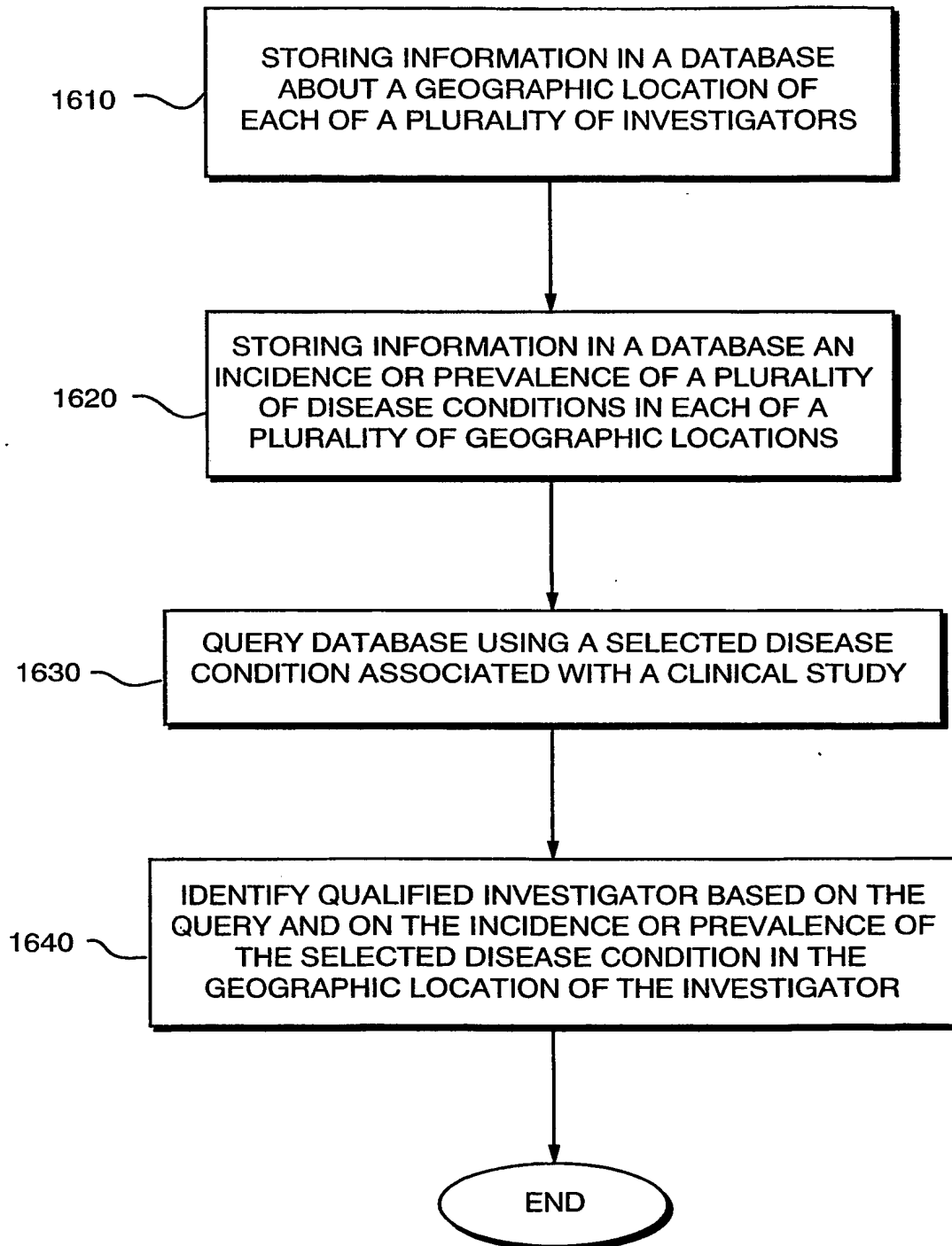


FIG. 16

SUBSTITUTE SHEET (RULE 26)

68/114

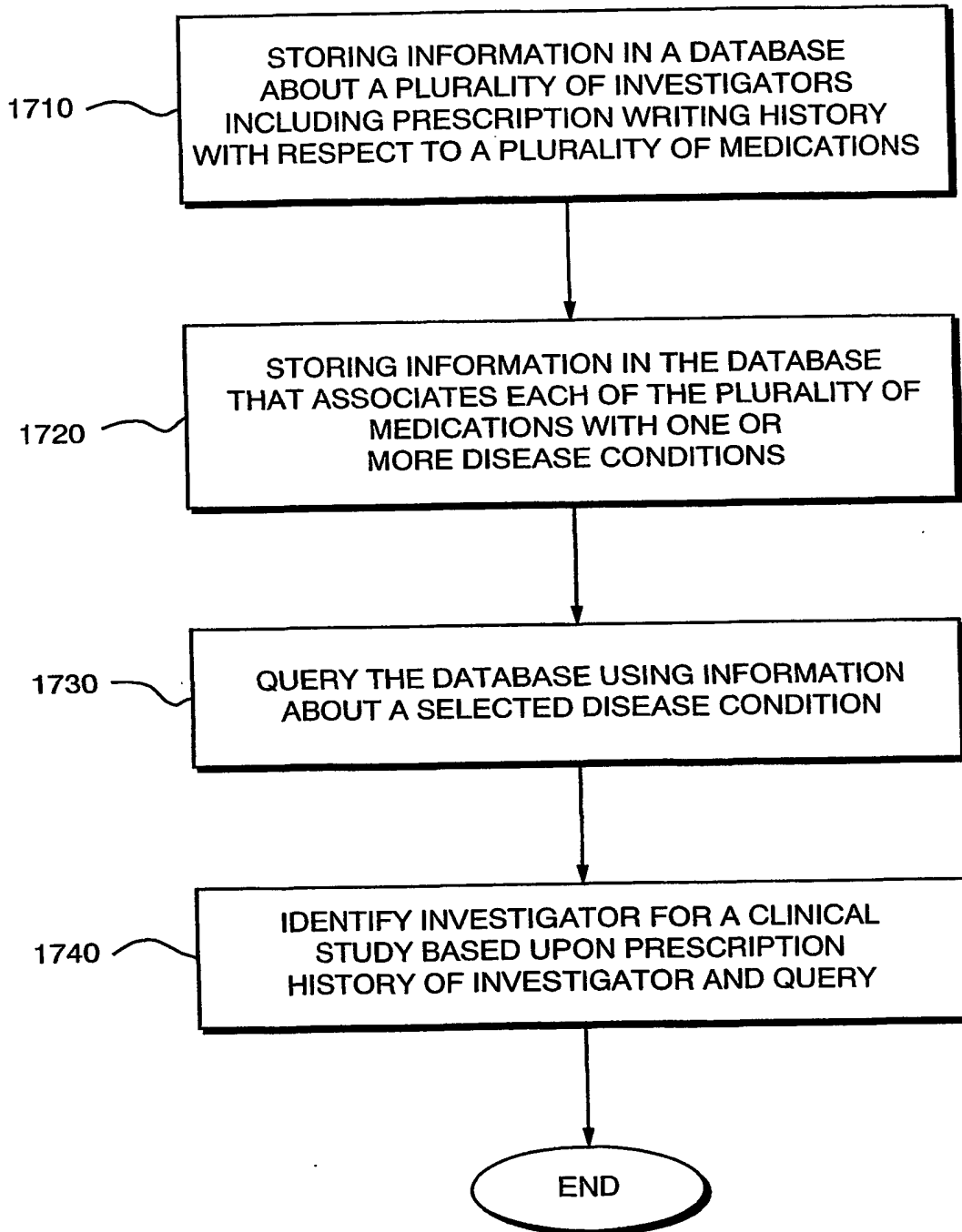


FIG. 17



69/114

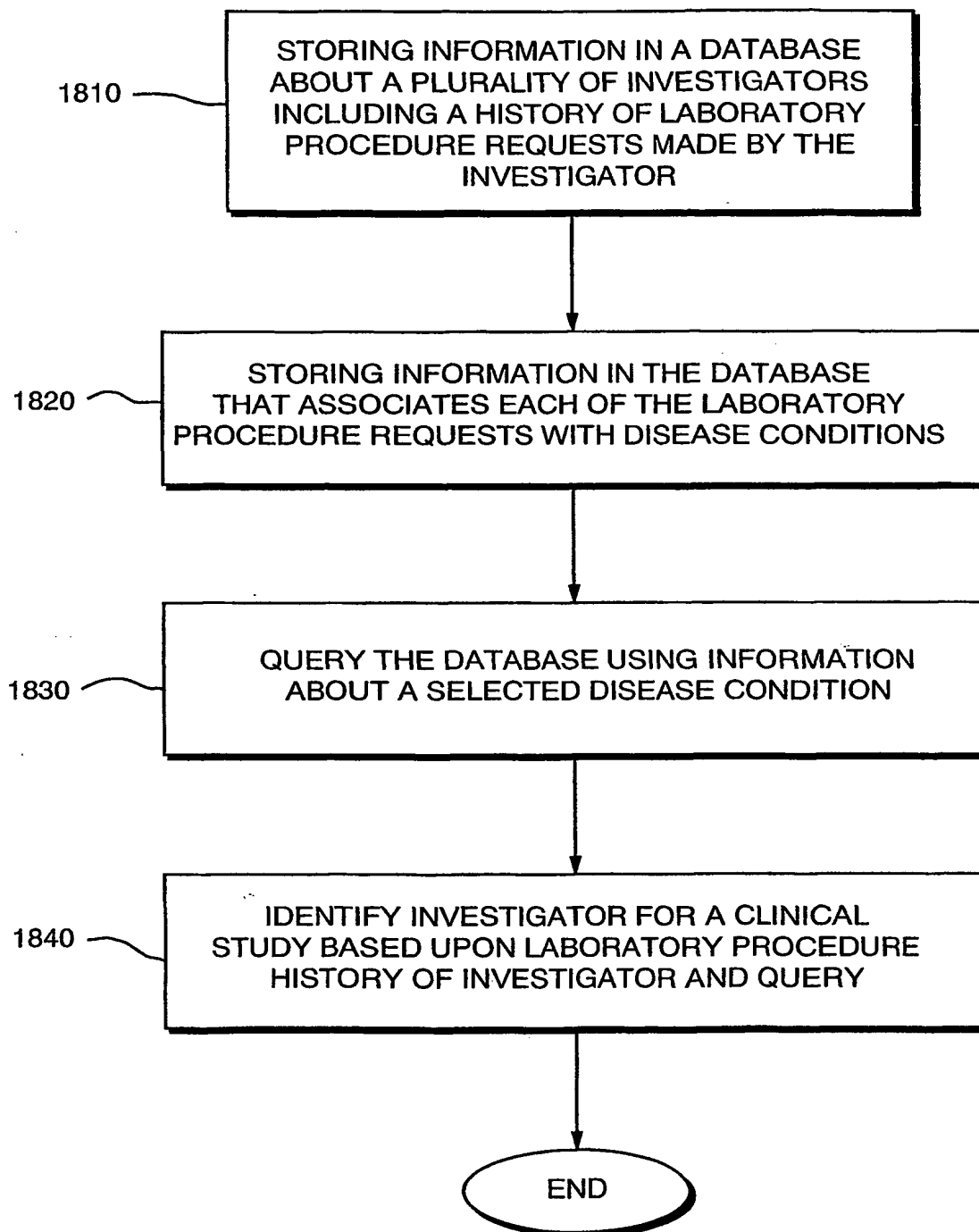


FIG. 18

70/114

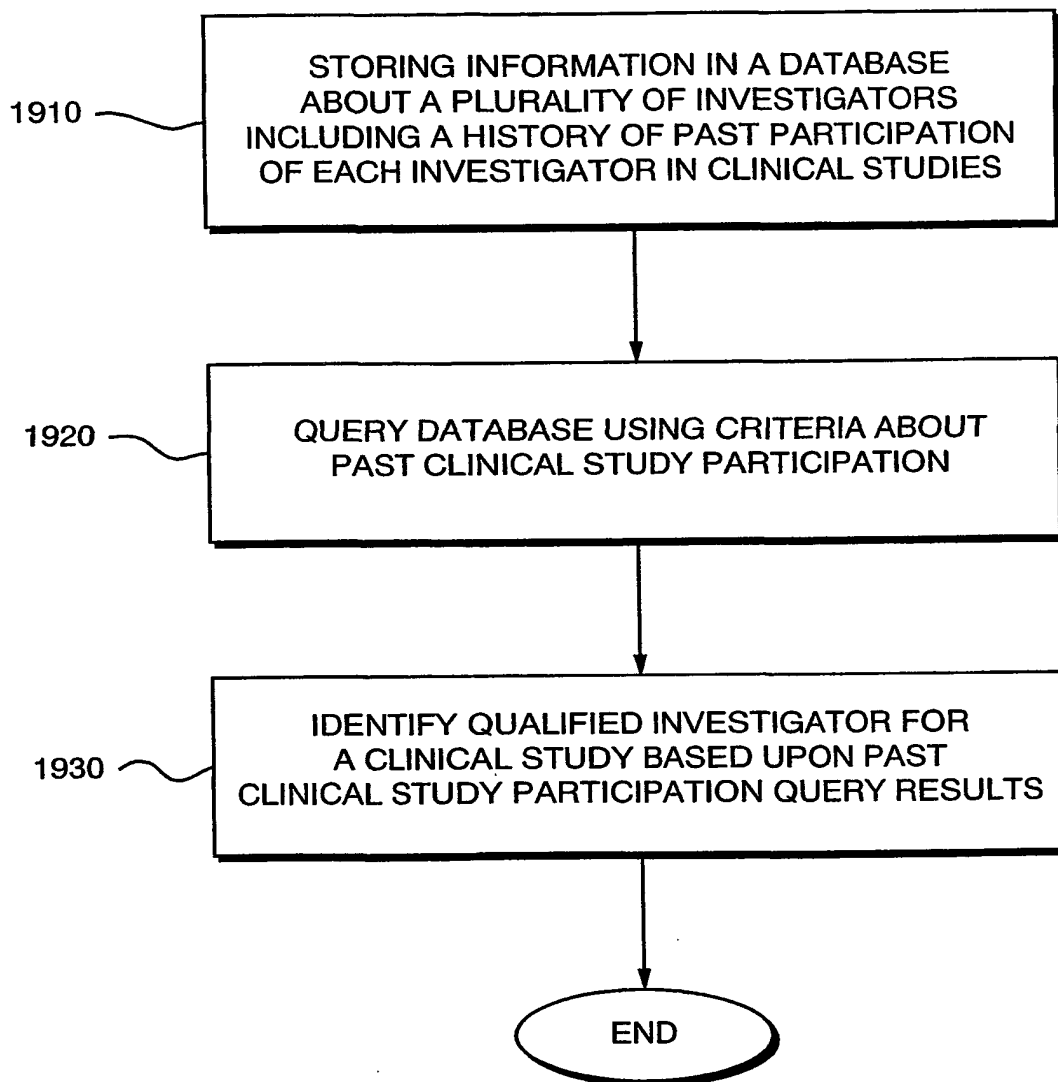


FIG. 19

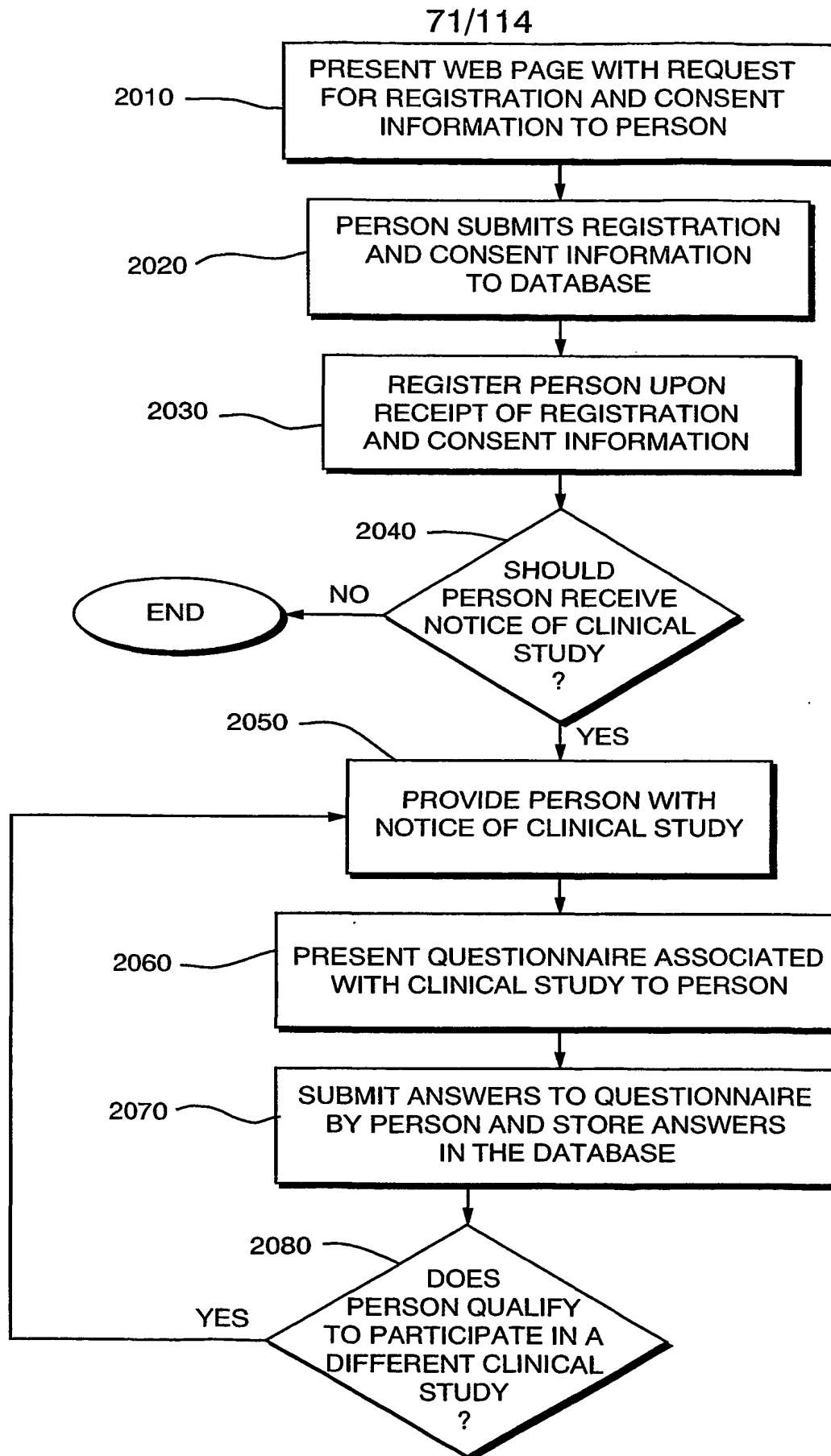


FIG. 20

72/114

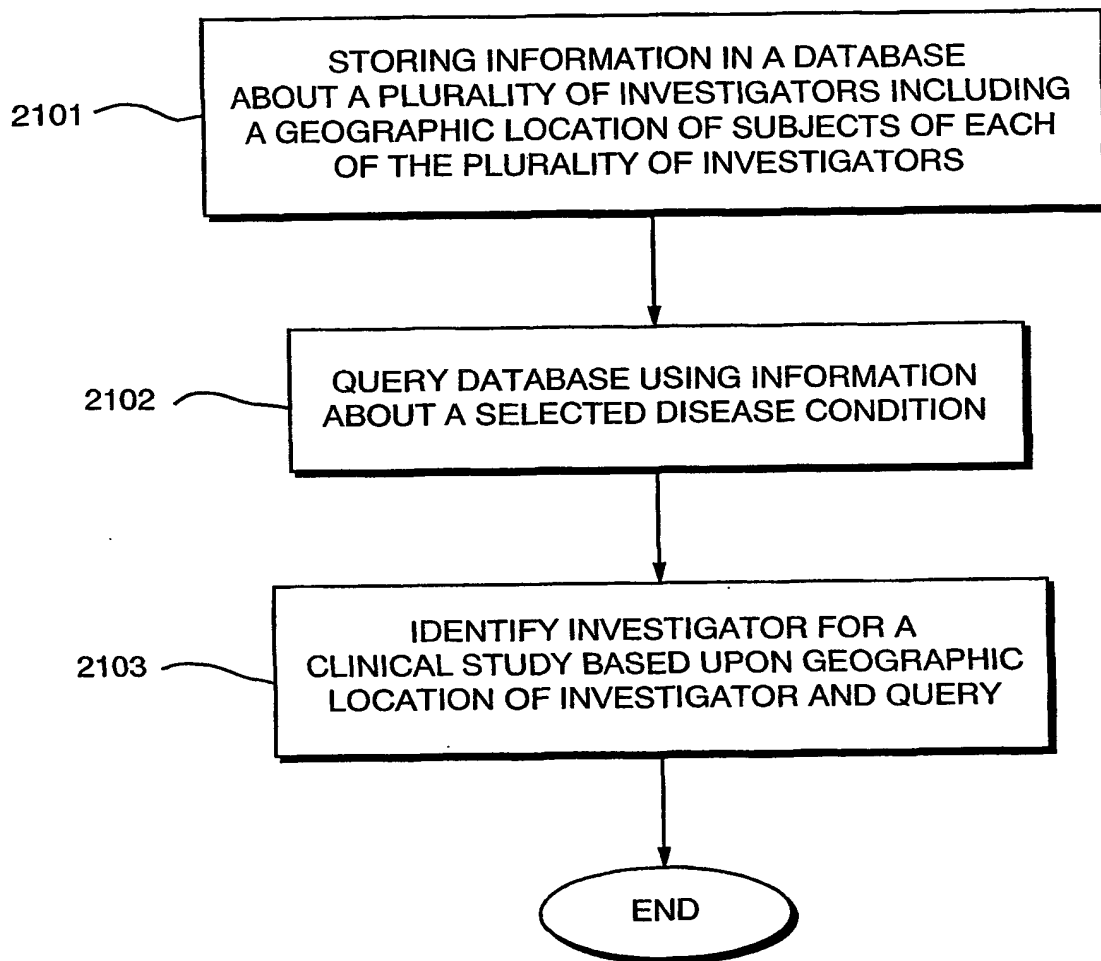


FIG. 21A

73/114

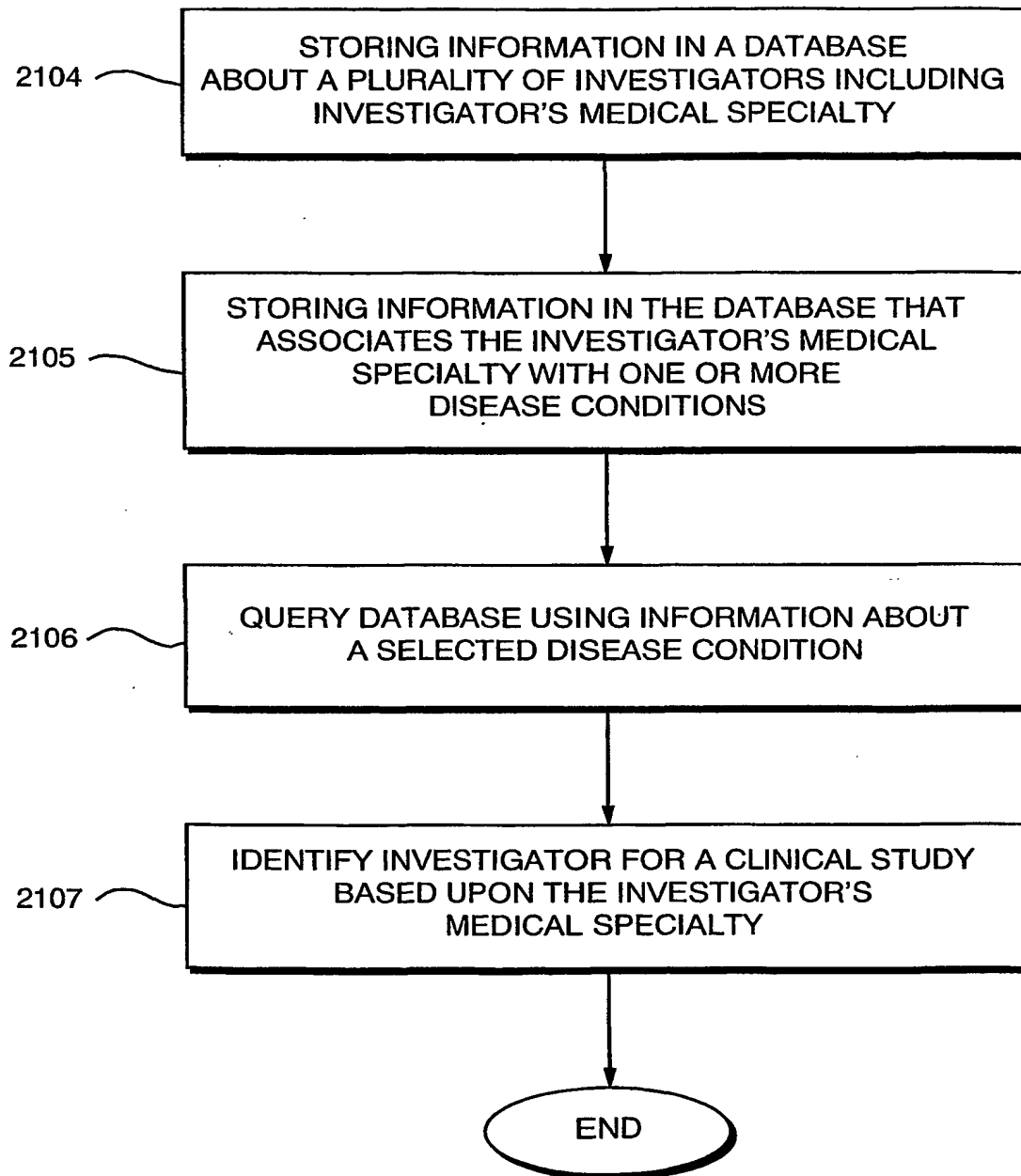


FIG. 21B

74/114

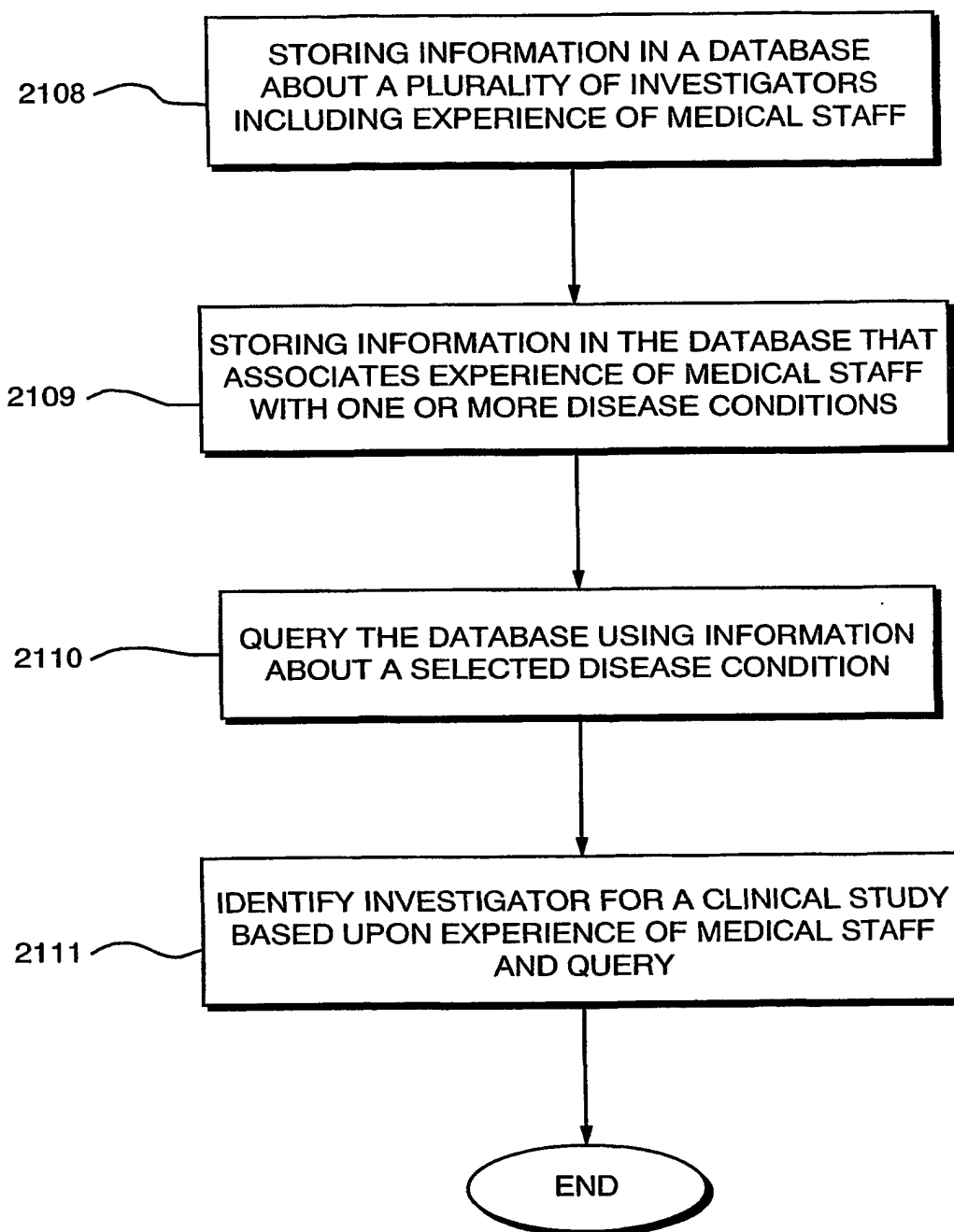


FIG. 21C

75/114

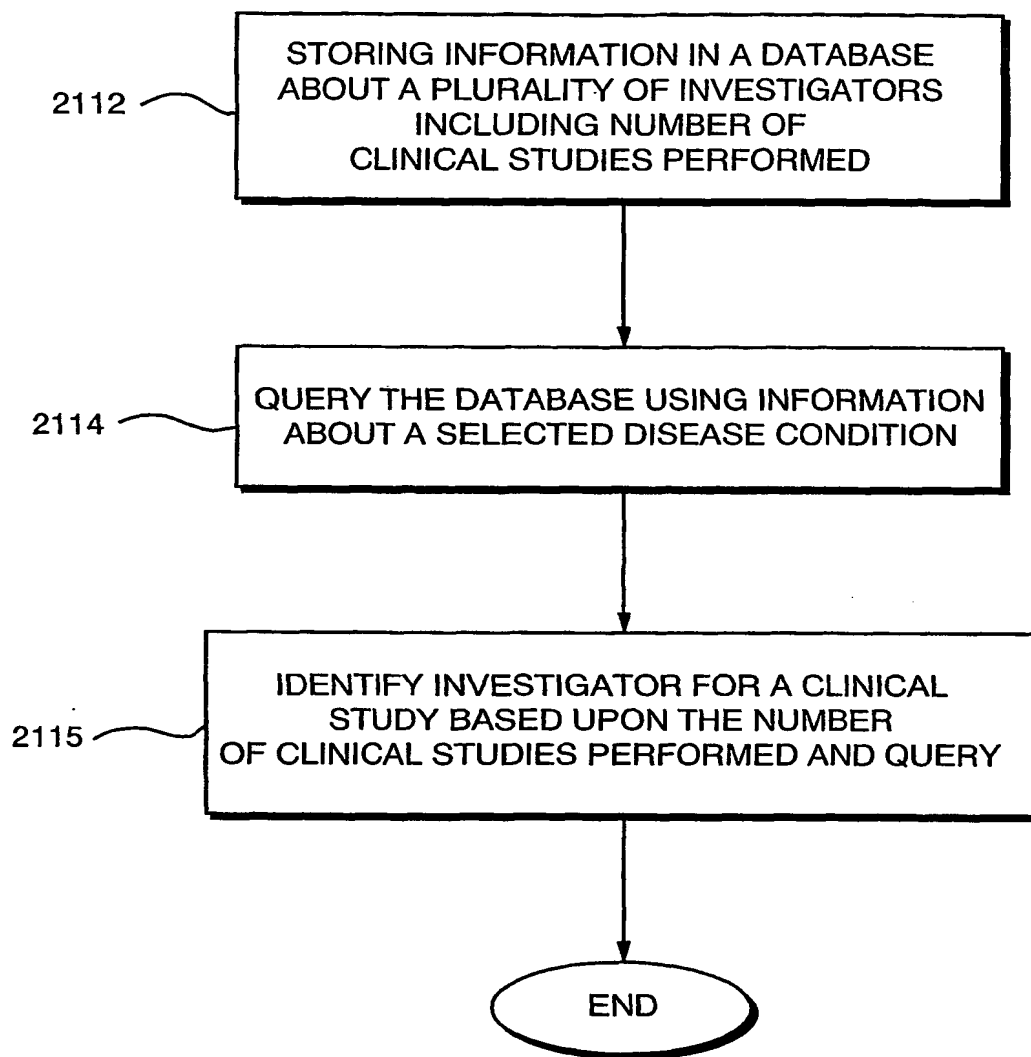


FIG. 21D

76/114

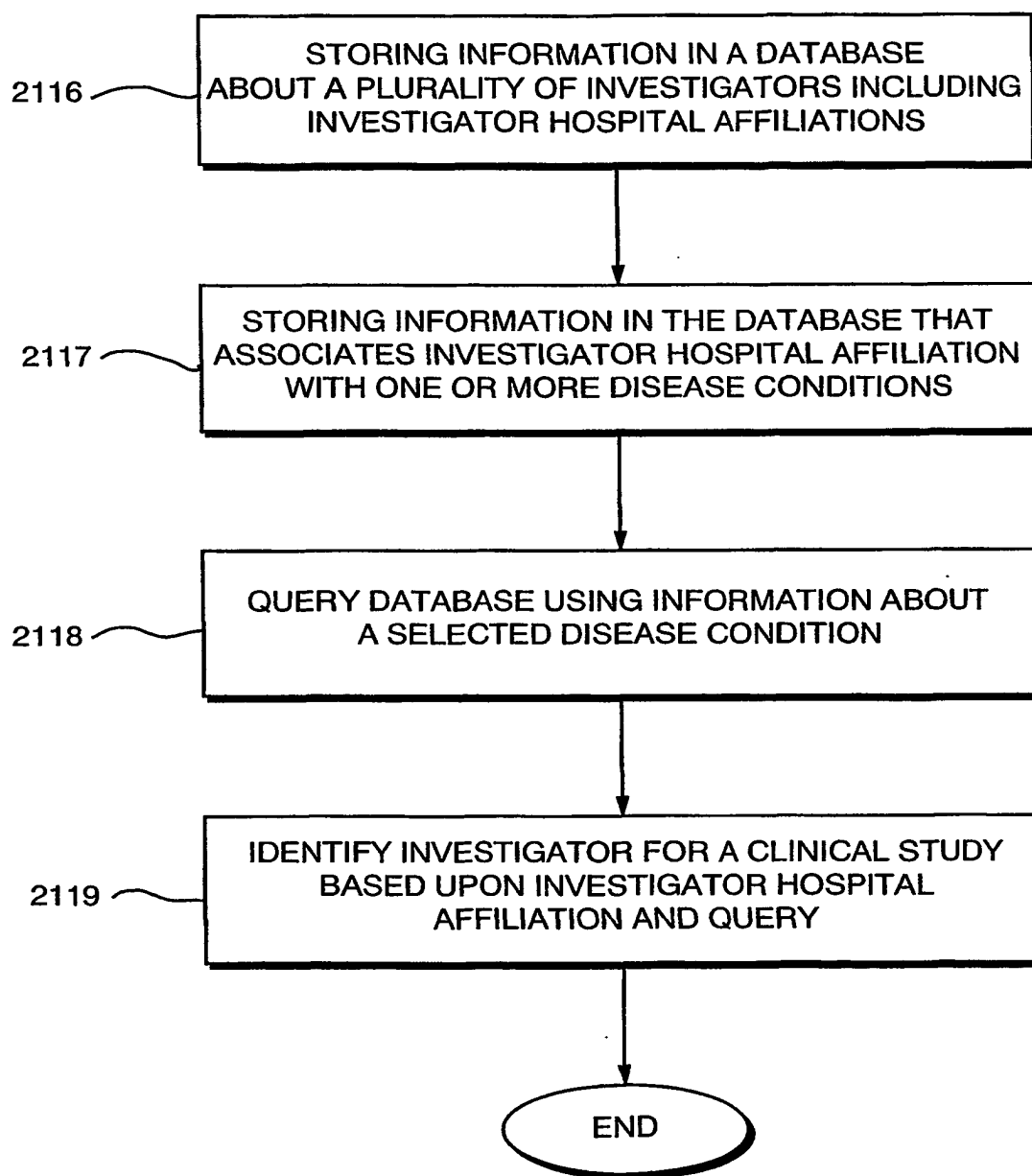


FIG. 21E



77/114

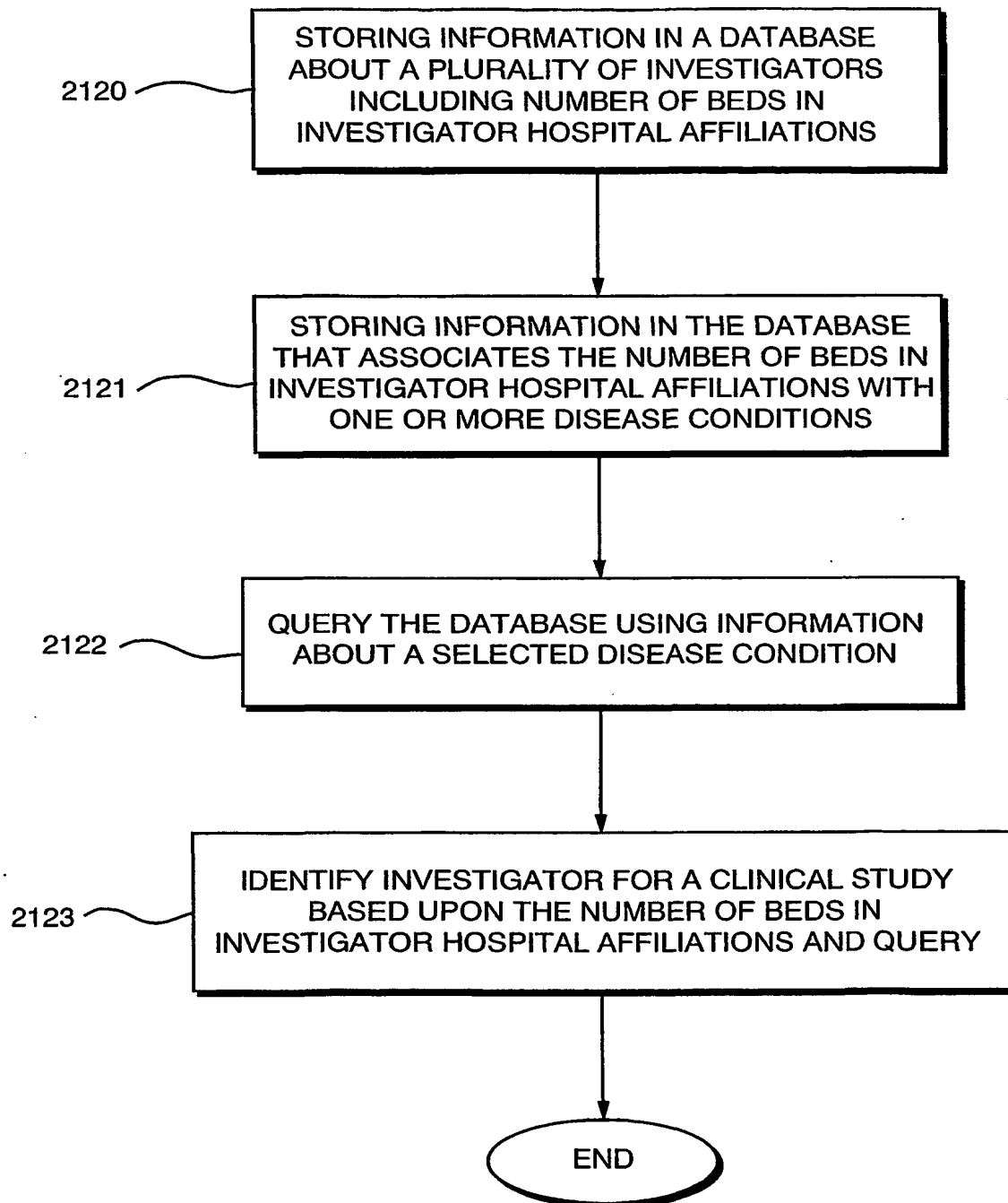


FIG. 21F

78/114

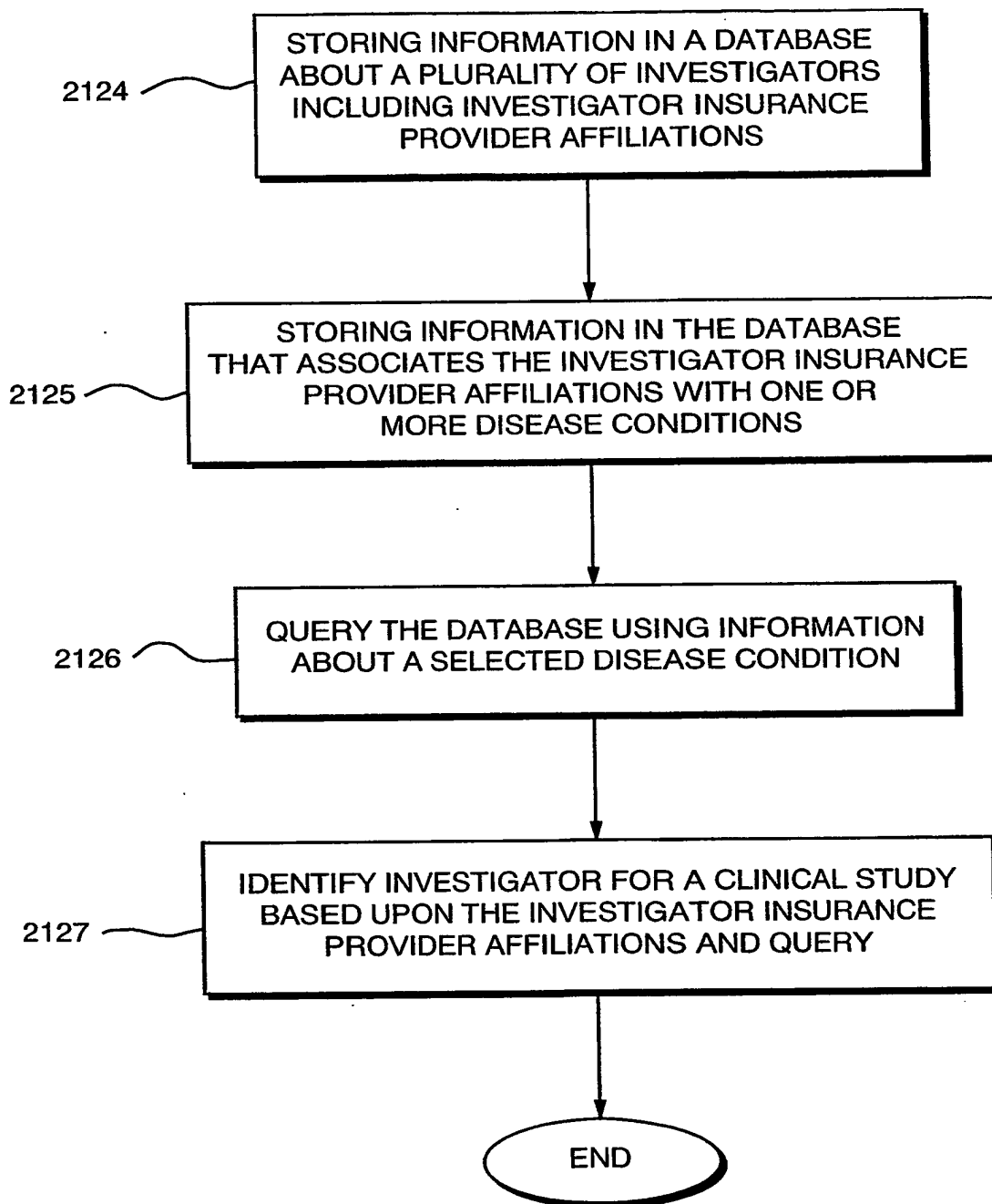


FIG. 21G

79/114

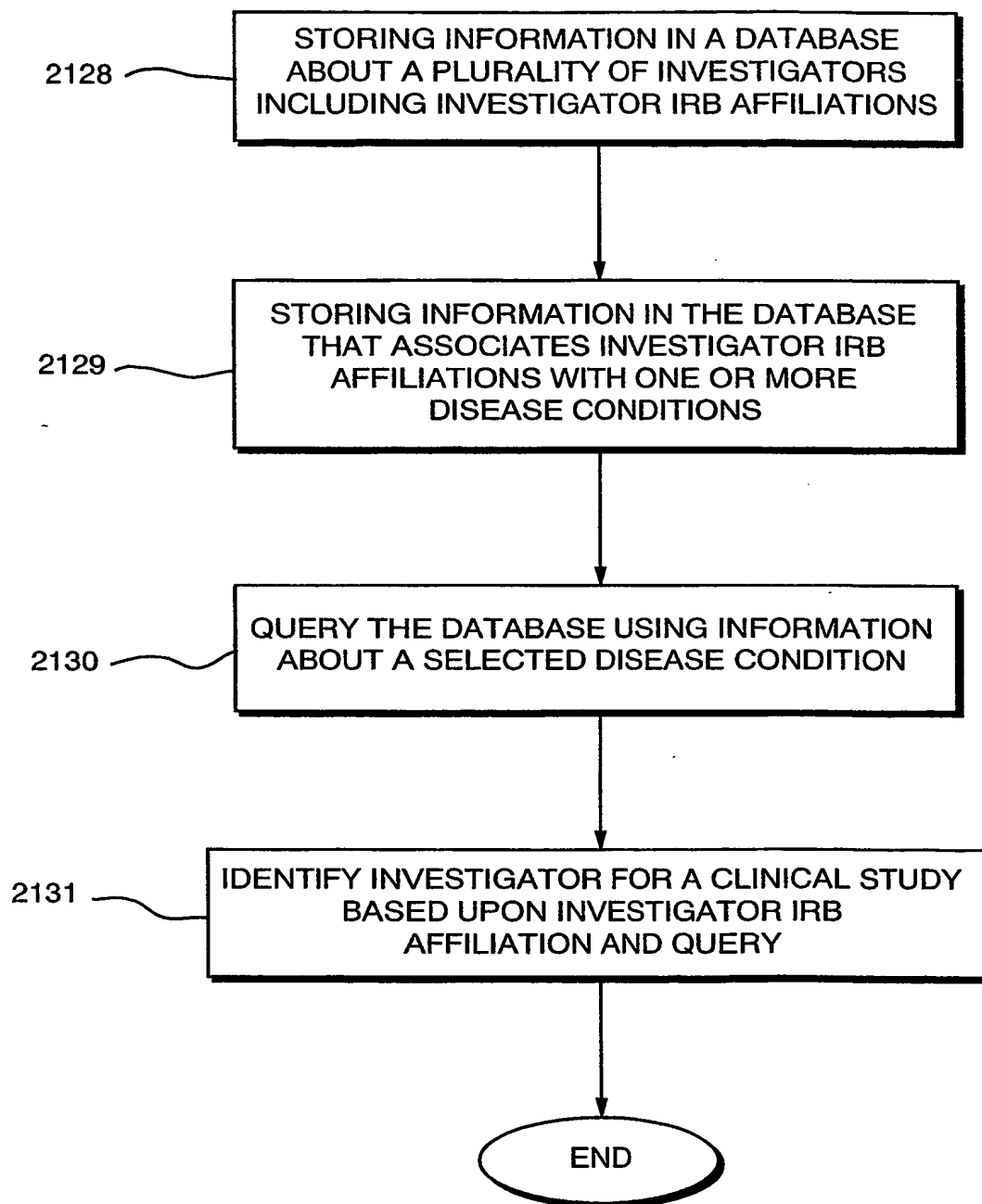


FIG. 21H

80/114

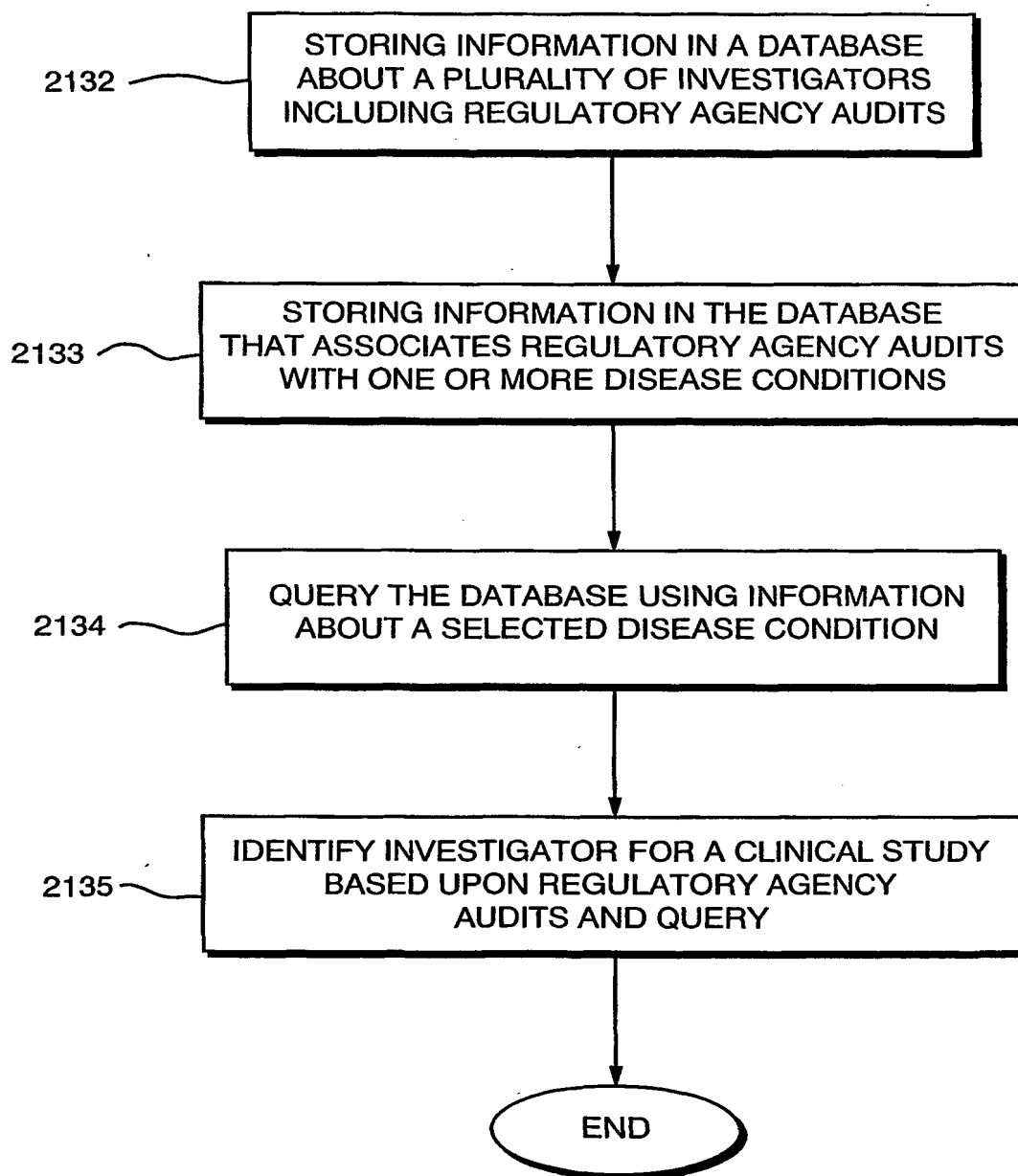


FIG. 211

81/114

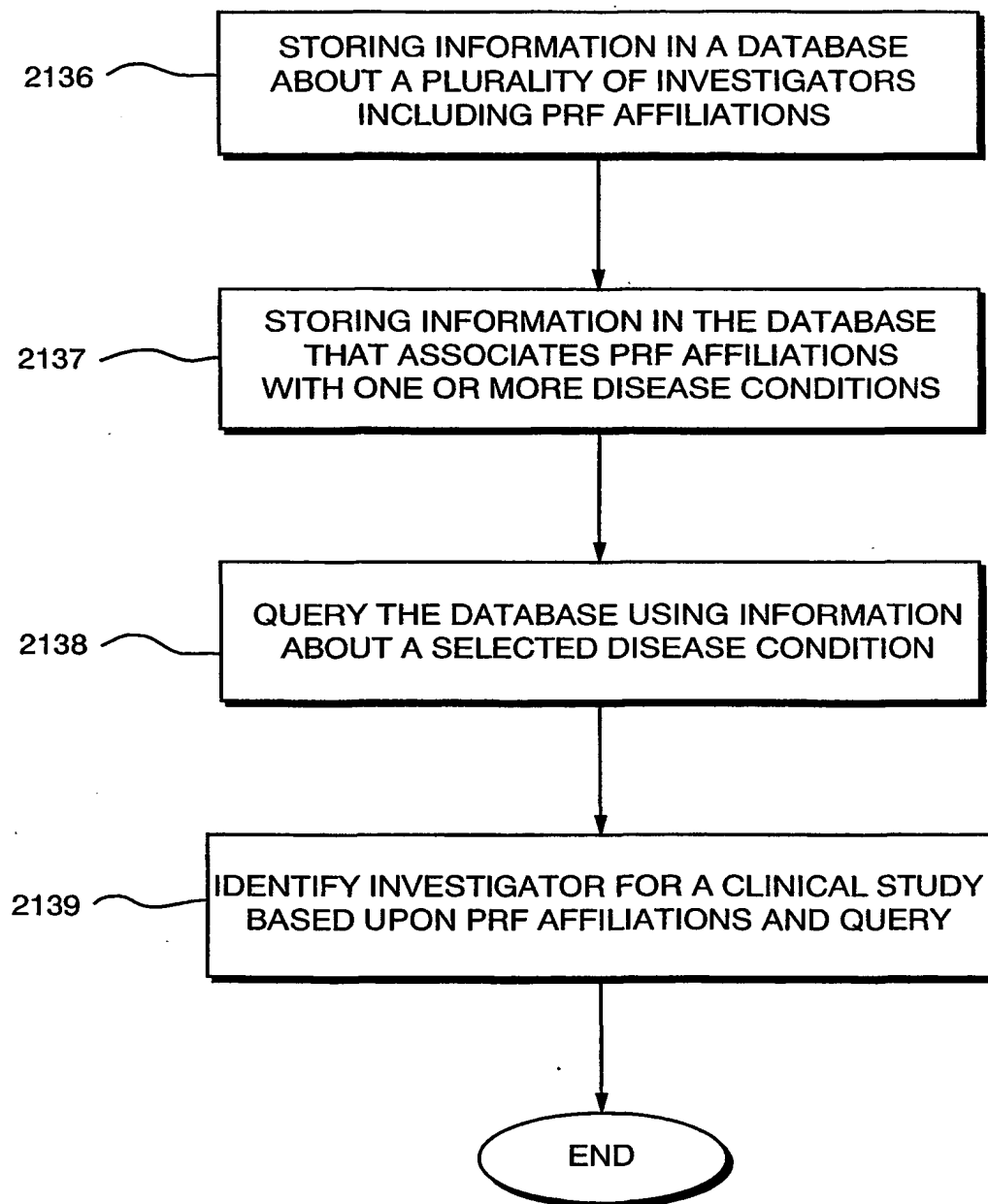


FIG. 21J

82/114

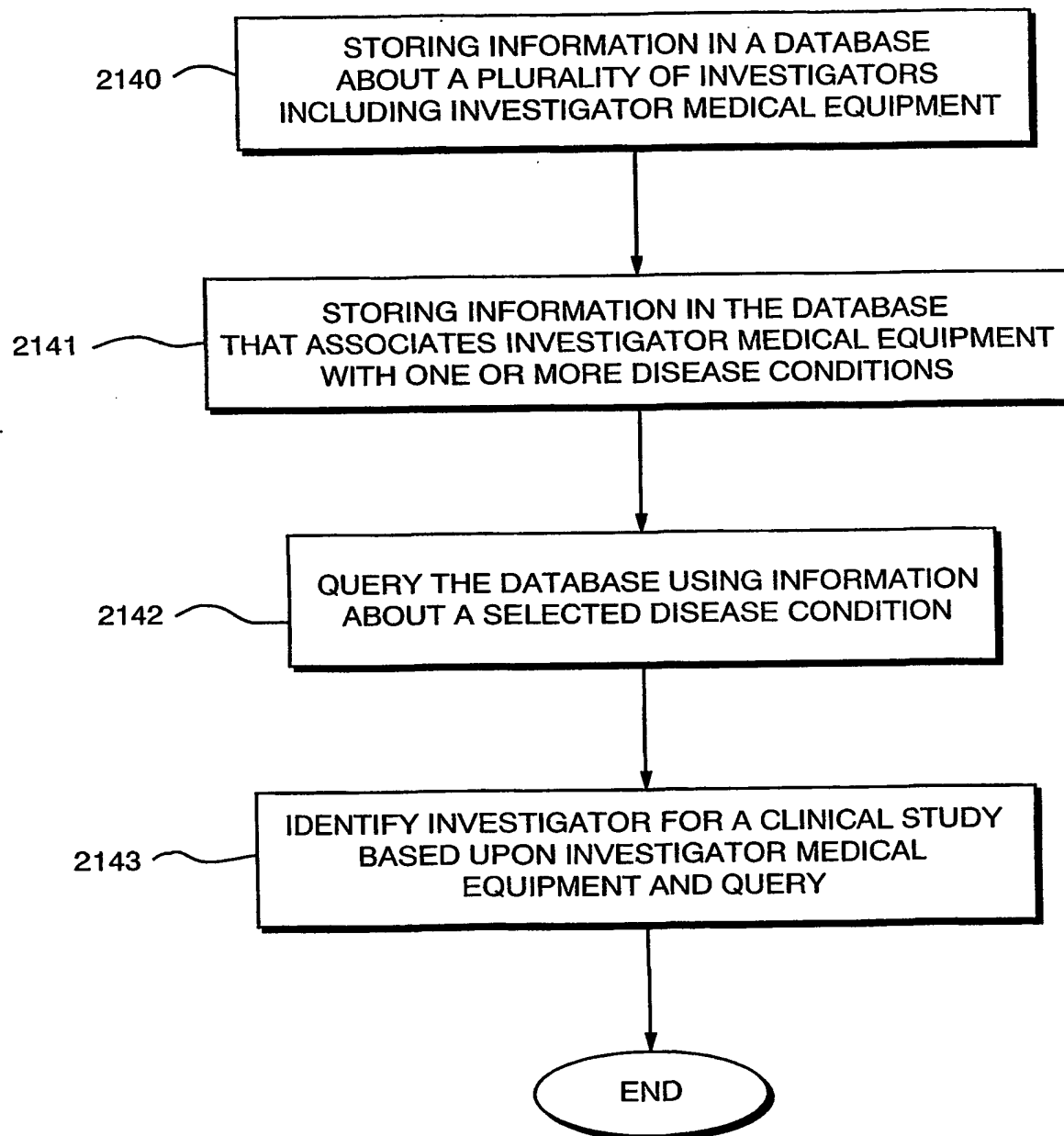


FIG. 21K

83/114

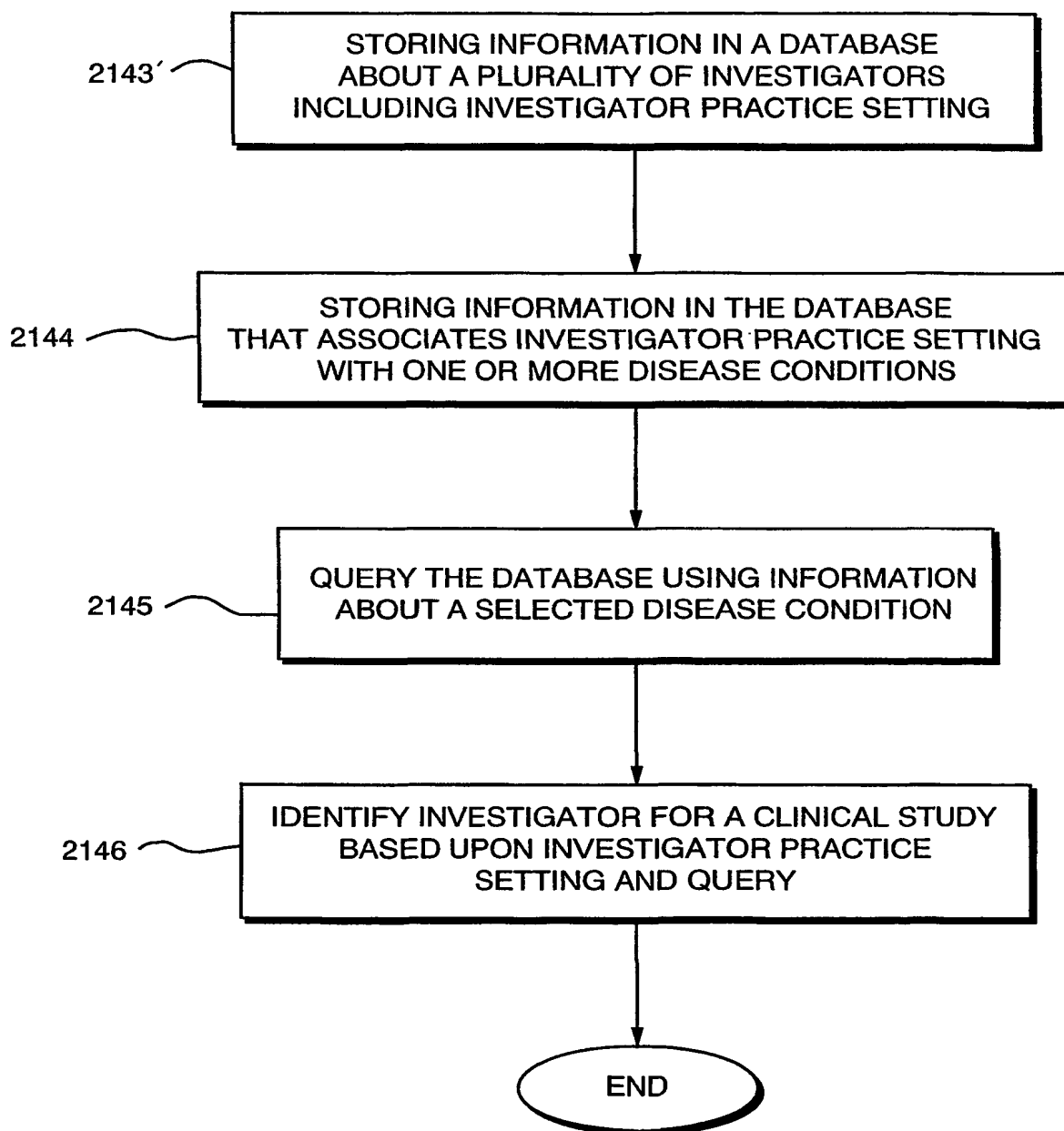


FIG. 21L

84/114

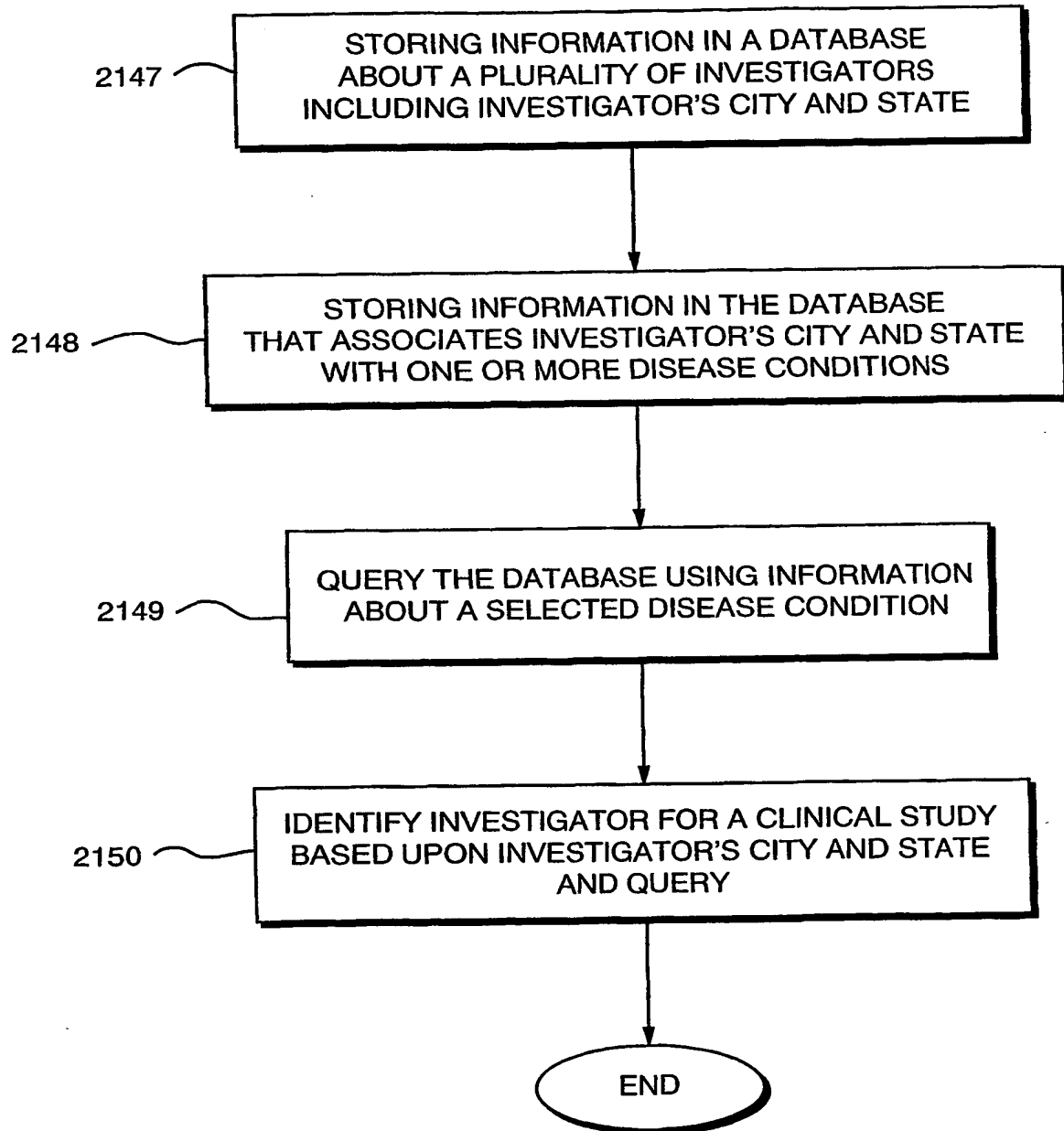


FIG. 21M



85/114

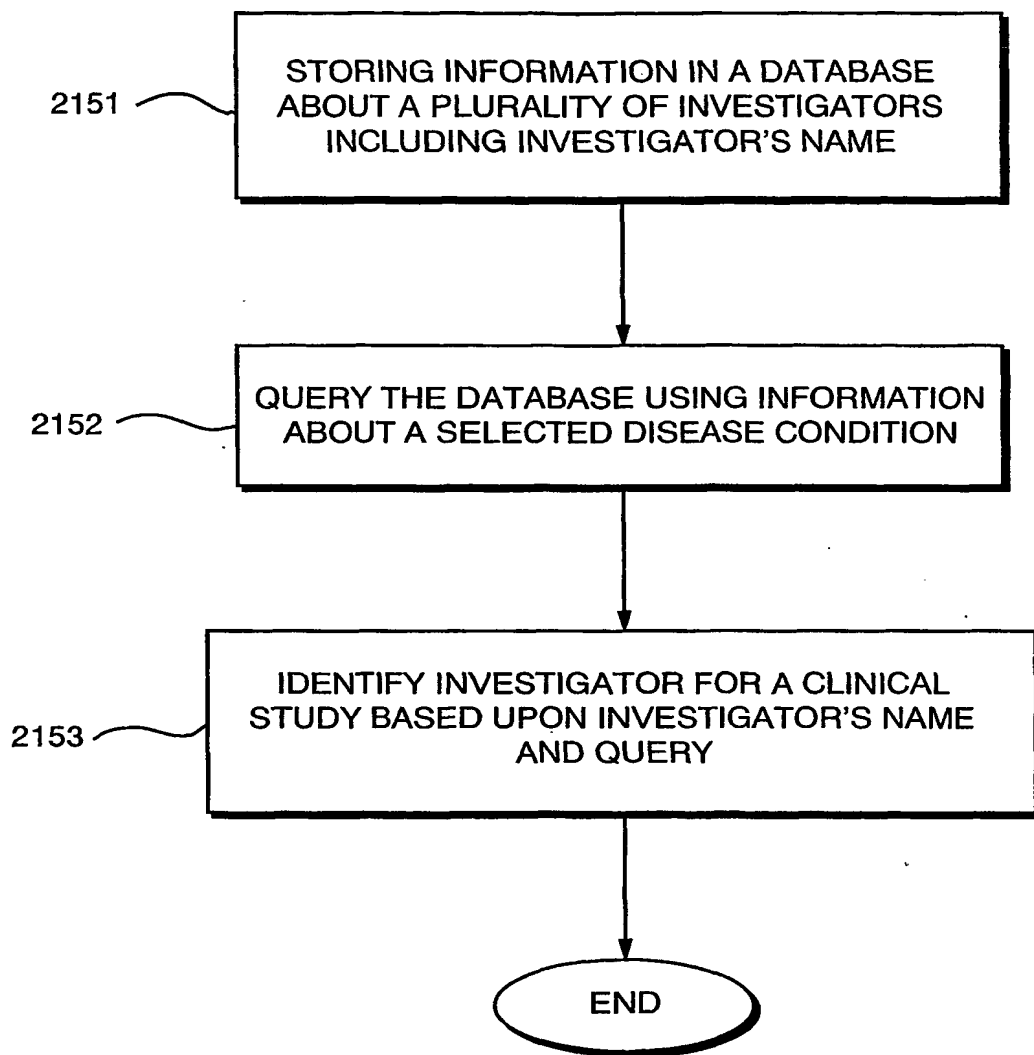


FIG. 21N

86/114

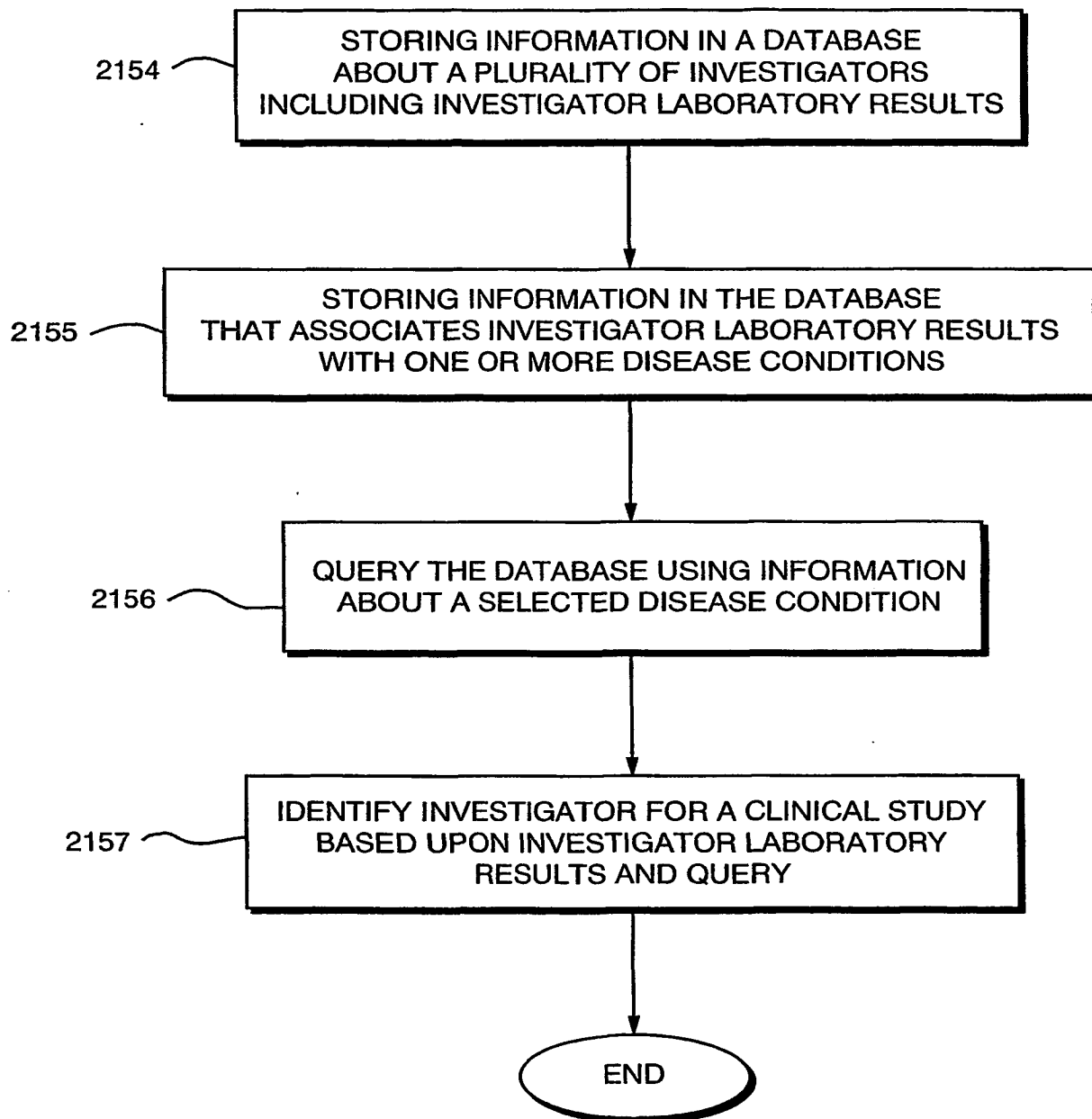


FIG. 210

87/114

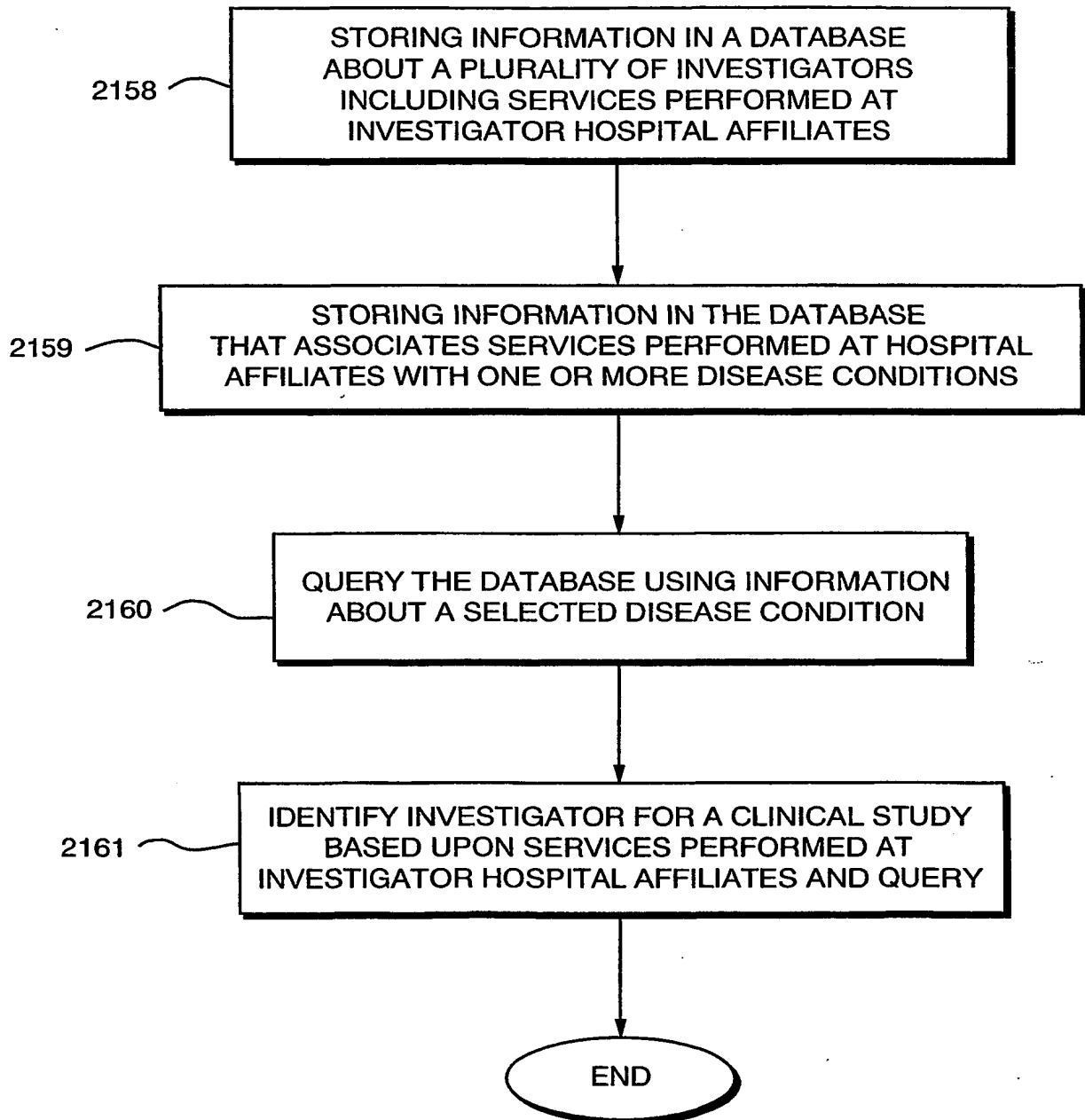


FIG. 21P

88/114

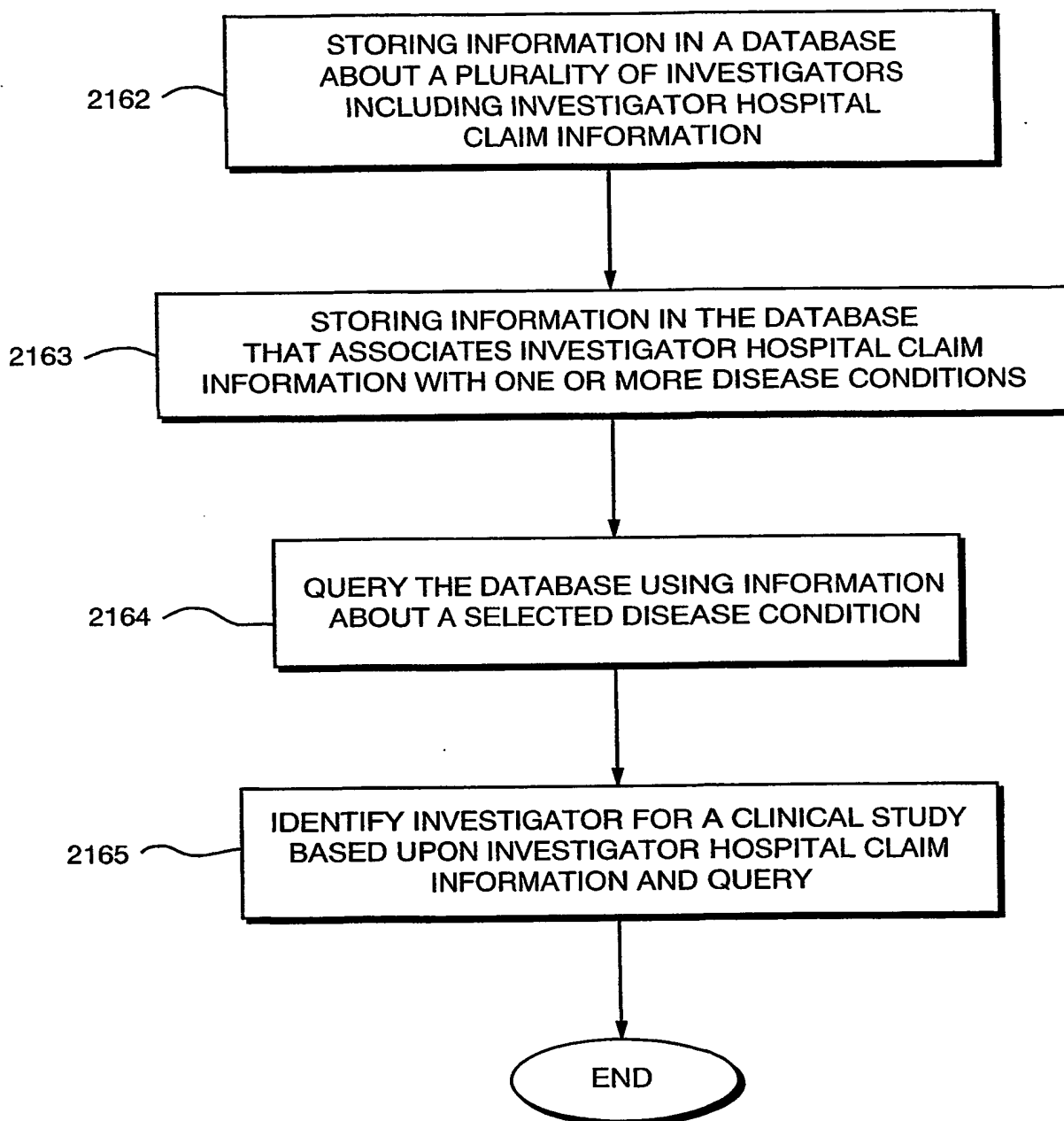


FIG. 21Q

## INV\_STUDY\_PERFORMANCE

89/114

INVESTIGATOR\_ID: CHAR(18)  
STUDY\_PRF\_ID: CHAR(18)

2220

SOURCE\_CD: CHAR(18)  
SPONSOR\_ID: CHAR(18)  
SPONSOR\_CRO\_NAME: CHAR(18)  
PROTOCOL\_NUMBER: CHAR(18)  
STUDY\_PHASE\_CD: CHAR(18)  
DRUG\_NAME: CHAR(18)  
DRUG\_CLASS: CHAR(18)  
THERA\_CONDITION\_CD: CHAR(18)  
START\_DATE: CHAR(18)  
NUM\_ENROLLMENT\_COMMITMENT: CHAR(18)  
NUM\_PATIENTS\_ENROLLED: CHAR(18)  
ENROLLMENT\_MONTHS: CHAR(18)  
ENROLLMENT\_MET\_IND: CHAR(18)  
TIMEFRAME\_MET\_IND: CHAR(18)  
PLACEBO\_RESPONSE\_RATE: CHAR(18)  
NUM\_PATIENTS\_EVALUABLE: CHAR(18)  
MICROBIOLOGIC\_EVALUABLE: CHAR(18)  
BACTERIAL\_EVALUABLE: CHAR(18)  
NOTES: CHAR(18)  
CREATE\_DATE: CHAR(18)  
UPDATE\_DATE: CHAR(18)  
CREATE\_BY: CHAR(18)  
UPDATE\_BY: CHAR(18)

## INV\_SPECIALTY

INVESTIGATOR\_ID: NUMBER(8)  
SPECIALTY\_CD: VARCHAR2(6)

2230

SOURCE\_CD: VARCHAR2(12)  
BOARD\_COMPLETE\_CD: VARCHAR2(12)  
CREATE\_DATE: DATE  
UPDATE\_DATE: DATE  
CREATE\_BY: INTEGER  
UPDATE\_BY: INTEGER

## INV\_PATIENT\_POPULATION

INVESTIGATOR\_ID: CHAR(18)  
INDICATION\_CD: CHAR2(18)

2240

ANNUAL\_PATIENTS\_TREATED: CHAR(18)  
ANNUAL\_NEW\_PATIENTS\_TREATED: CHAR(18)  
INTERESTED\_IND: CHAR(18)  
CREATE\_BY: CHAR(18)  
UPDATE\_BY: CHAR(18)  
CREATE\_DATE: CHAR(18)  
UPDATE\_DATE: CHAR(18)

TO 2210  
FIG. 22B

FIG. 22A

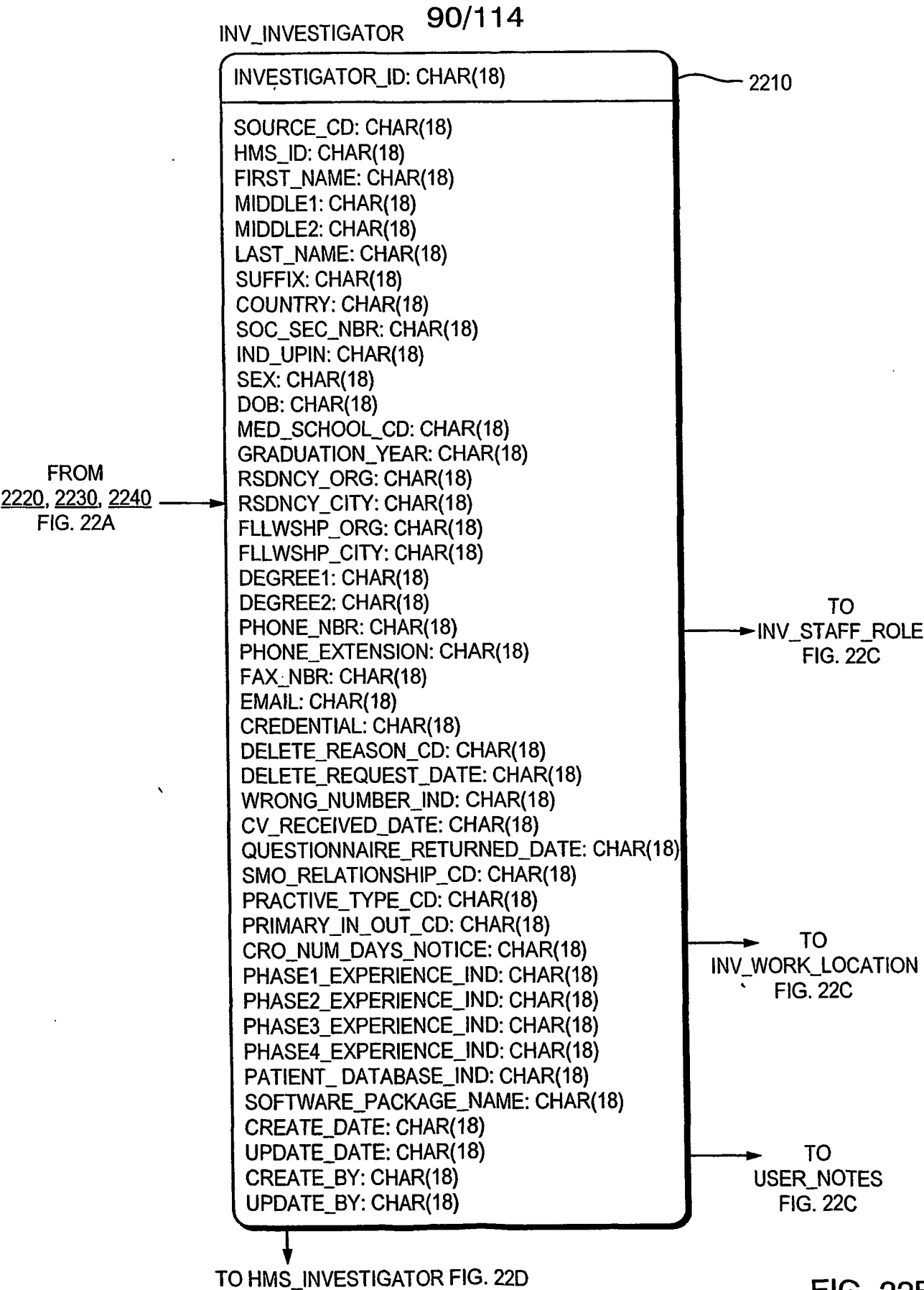
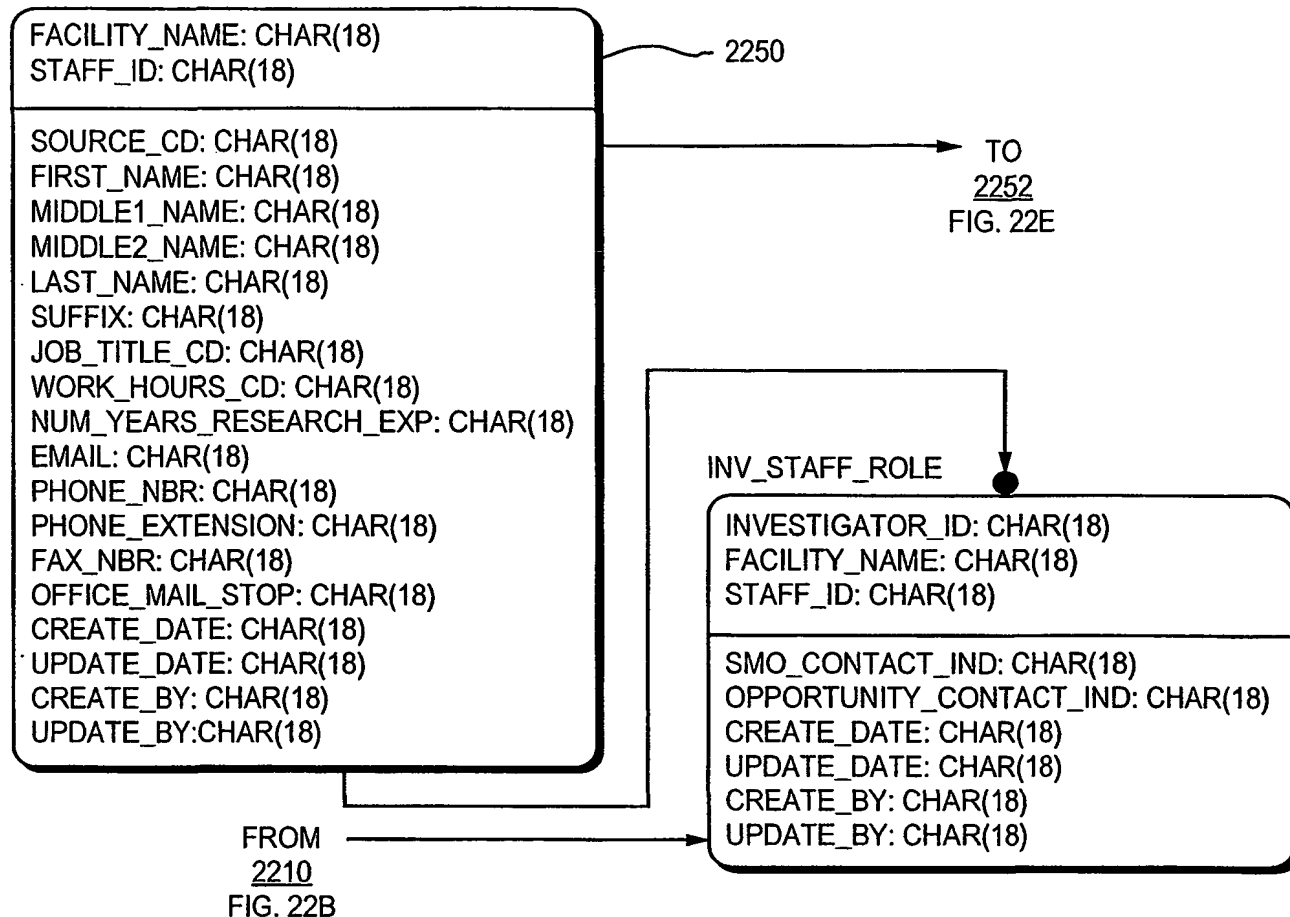


FIG. 22B

INV\_STUDY\_STAFF

91/114



INV\_WORK\_LOCATION

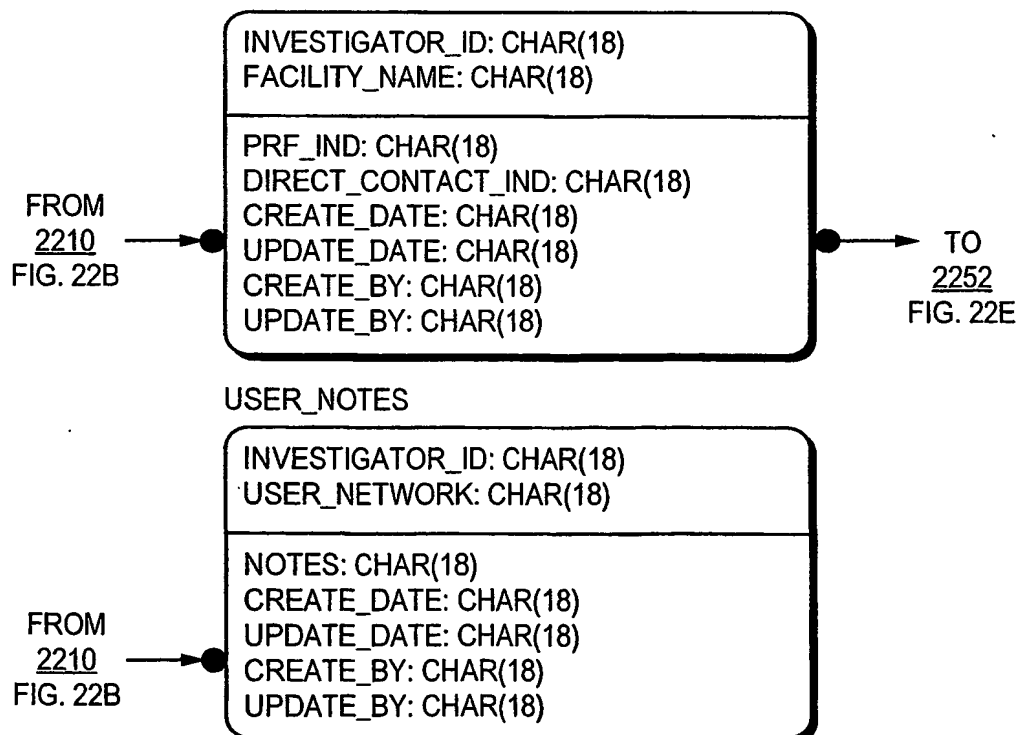


FIG. 22C

92/114

FROM  
2210  
FIG. 22B

HMS\_INVESTIGATOR

CONTACT\_ID: NUMBER(7)  
INVESTIGATOR\_ID: CHAR(18)

HMS\_ID: VARCHAR2(12)  
SOC\_SEC\_NBR: NUMBER(9)  
IND\_UPIN: VARCHAR2(7)  
FIRST\_NAME: VARCHAR2(25)  
MIDDLE\_NAME\_1: VARCHAR2(25)  
MIDDLE\_NAME\_2: VARCHAR2(25)  
LAST\_NAME: VARCHAR2(50)  
SUFFIX: VARCHAR2(10)  
CREDENTIAL: VARCHAR2(3)  
SEX: VARCHAR2(1)  
DOB: NUMBER(10)  
MED\_SCHOOL\_CD: VARCHAR2(8)  
GRADUATION\_YEAR: VARCHAR2(4)  
RSDNCY\_ORG: VARCHAR2(100)  
RSDNCY\_CITY: VARCHAR2(60)  
FLLWSHP\_ORG: VARCHAR2(100)  
FLLWSHP\_CITY: VARCHAR2(60)  
CREATION\_DATE: DATE  
UPDATE\_DATE: DATE  
CREDENTIAL\_2: VARCHAR2(3)  
INTRNSHP\_NAME: VARCHAR2(100)  
INTRNSHP\_CITY: VARCHAR(60)  
INTRNSHP\_STATE: VARCHAR2(2)  
UPIN\_SANC: VARCHAR2(50)  
STATE\_SANC: VARCHAR2(50)  
RSDNCY\_STATE: VARCHAR2(2)  
FLLWSHP\_STATE: VARCHAR2(2)

TO  
HMS\_HSPTL\_AFFLTN  
FIG. 22FTO  
HMS\_SPECIALTY  
FIG. 22FTO  
HMS\_DEA  
FIG. 22FTO  
HMS\_BOARD\_CERT  
FIG. 22FTO  
HMS\_LANGUAGE  
FIG. 22FTO  
HMS\_INSURANCE\_AFFLTN  
FIG. 22GTO  
HMS\_GRP\_UPIN  
FIG. 22GTO  
HMS\_EMPLYR\_TAX\_ID  
FIG. 22GTO  
HMS\_INV\_ADDRESS  
FIG. 22HTO  
FDA\_1572  
FIG. 22HTO  
HMS\_LICENSE  
FIG. 22G

FIG. 22D



93/114

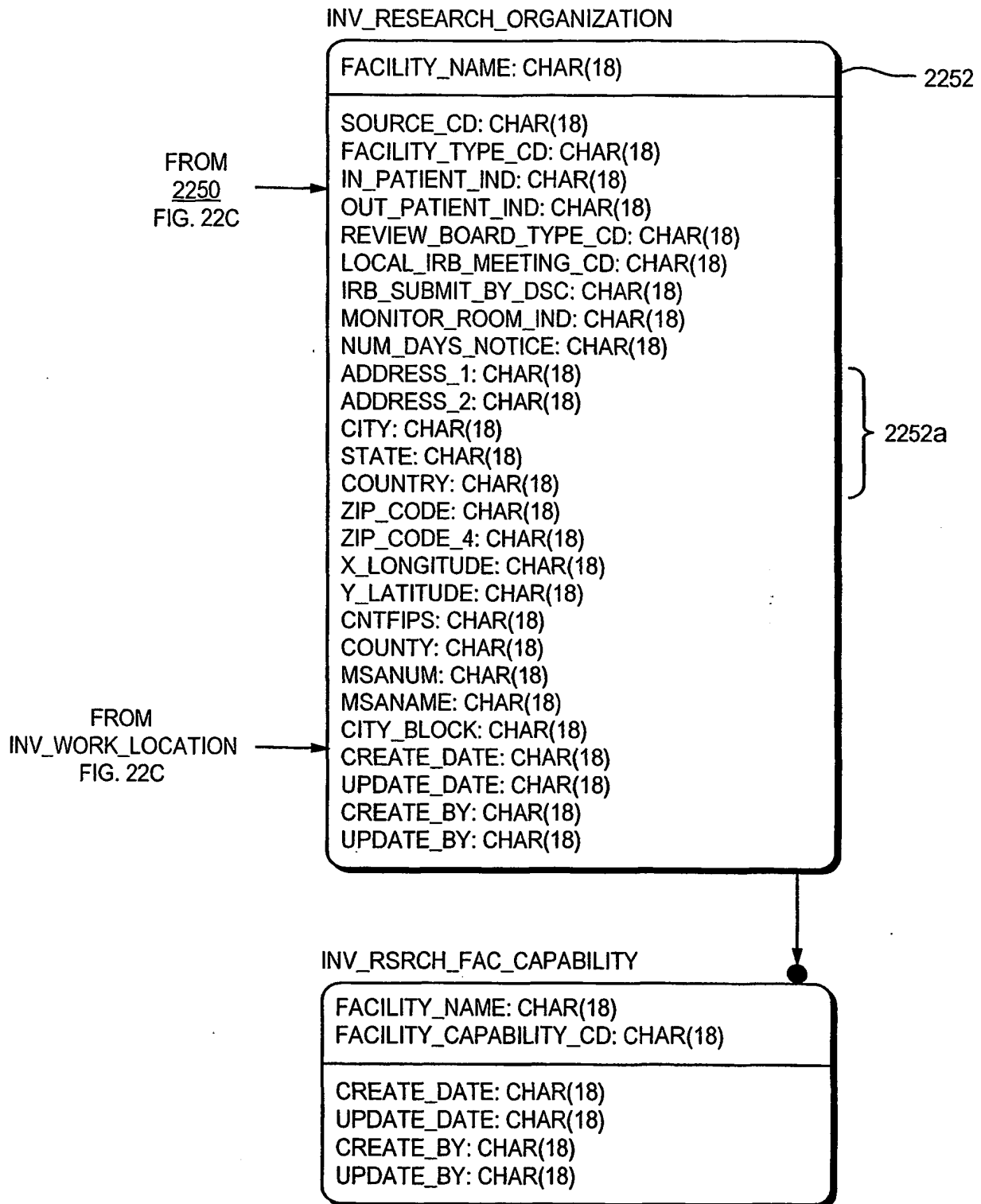


FIG. 22E

94/114

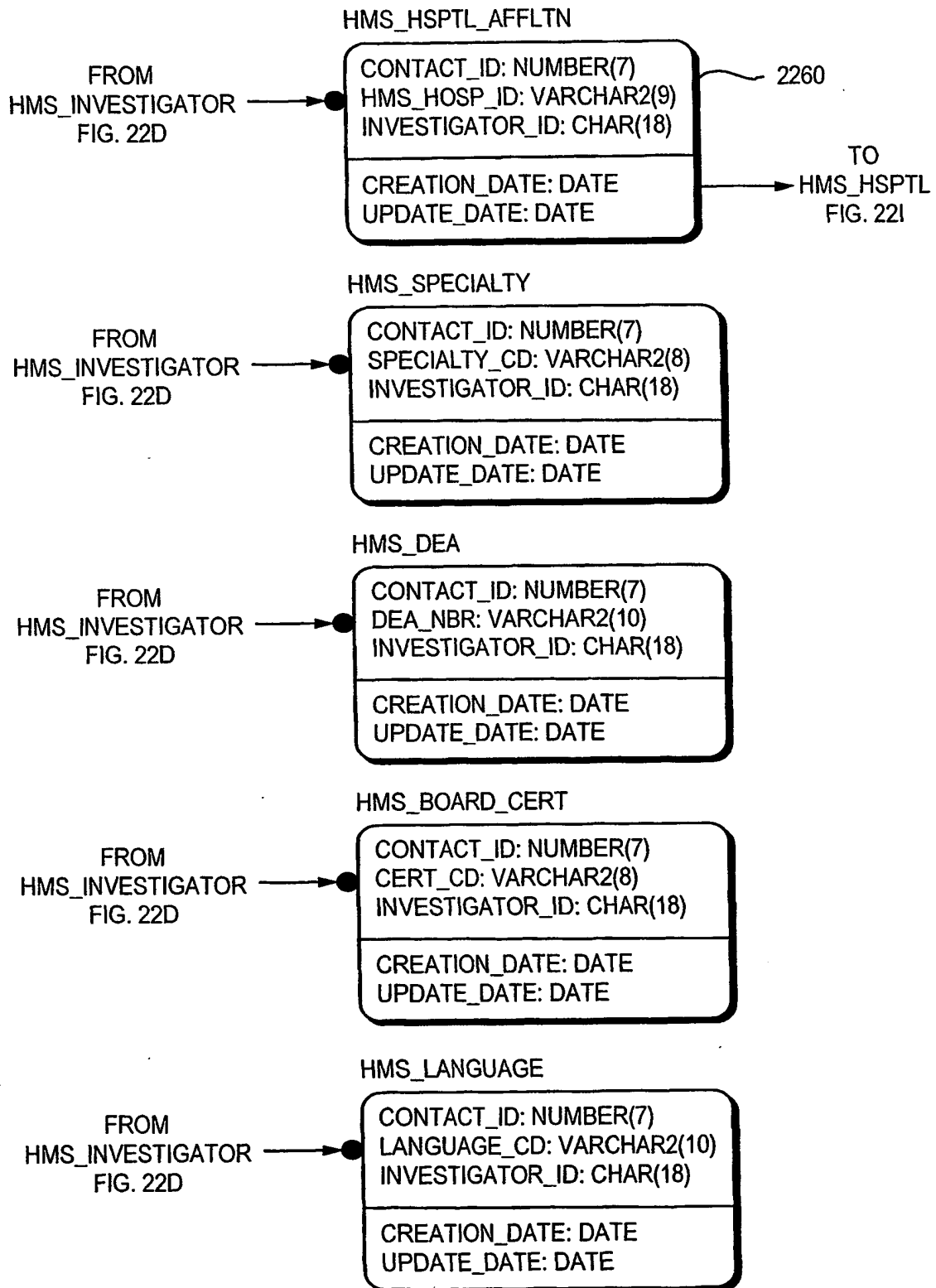


FIG. 22F

SUBSTITUTE SHEET (RULE 26)

95/114

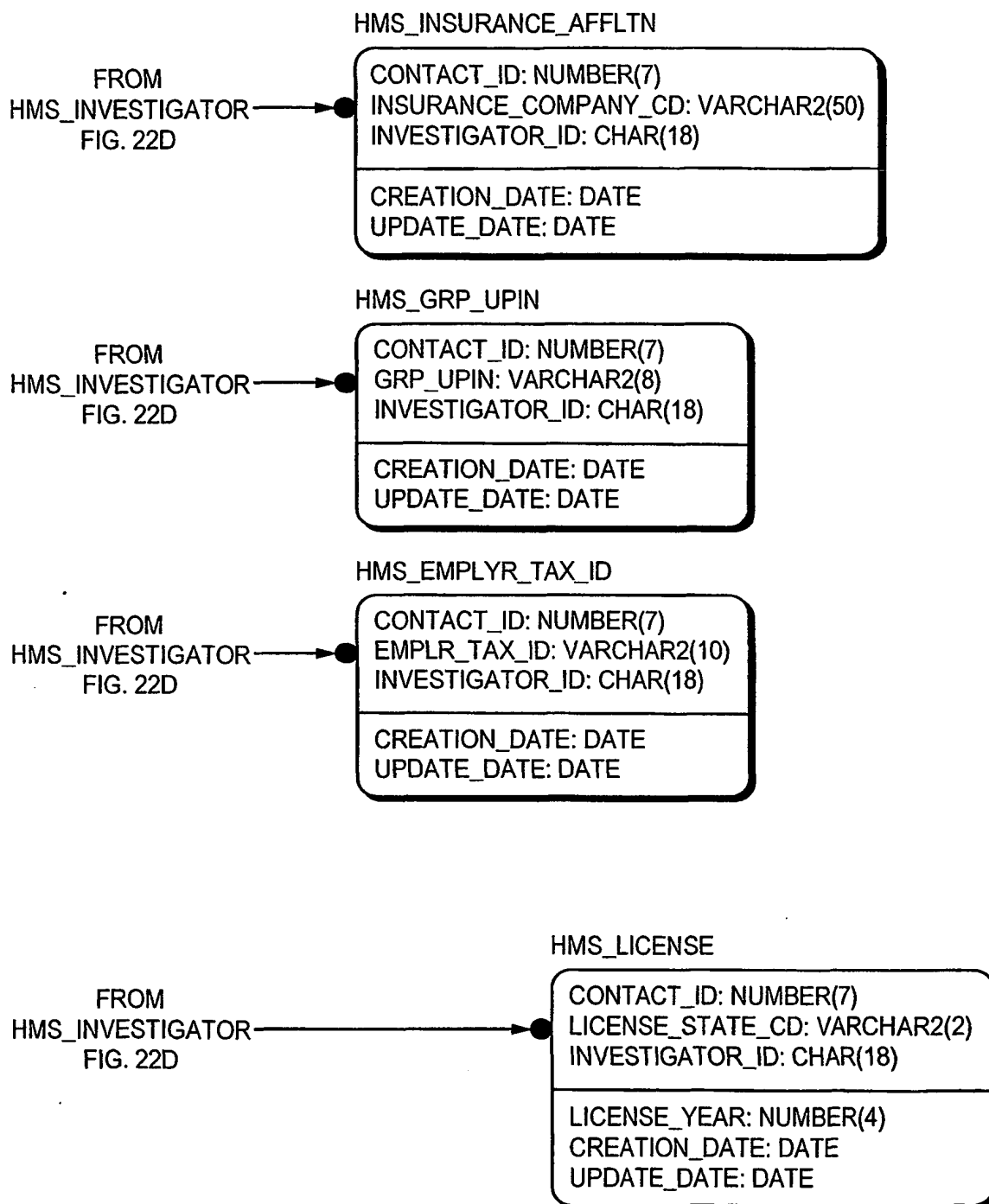


FIG. 22G

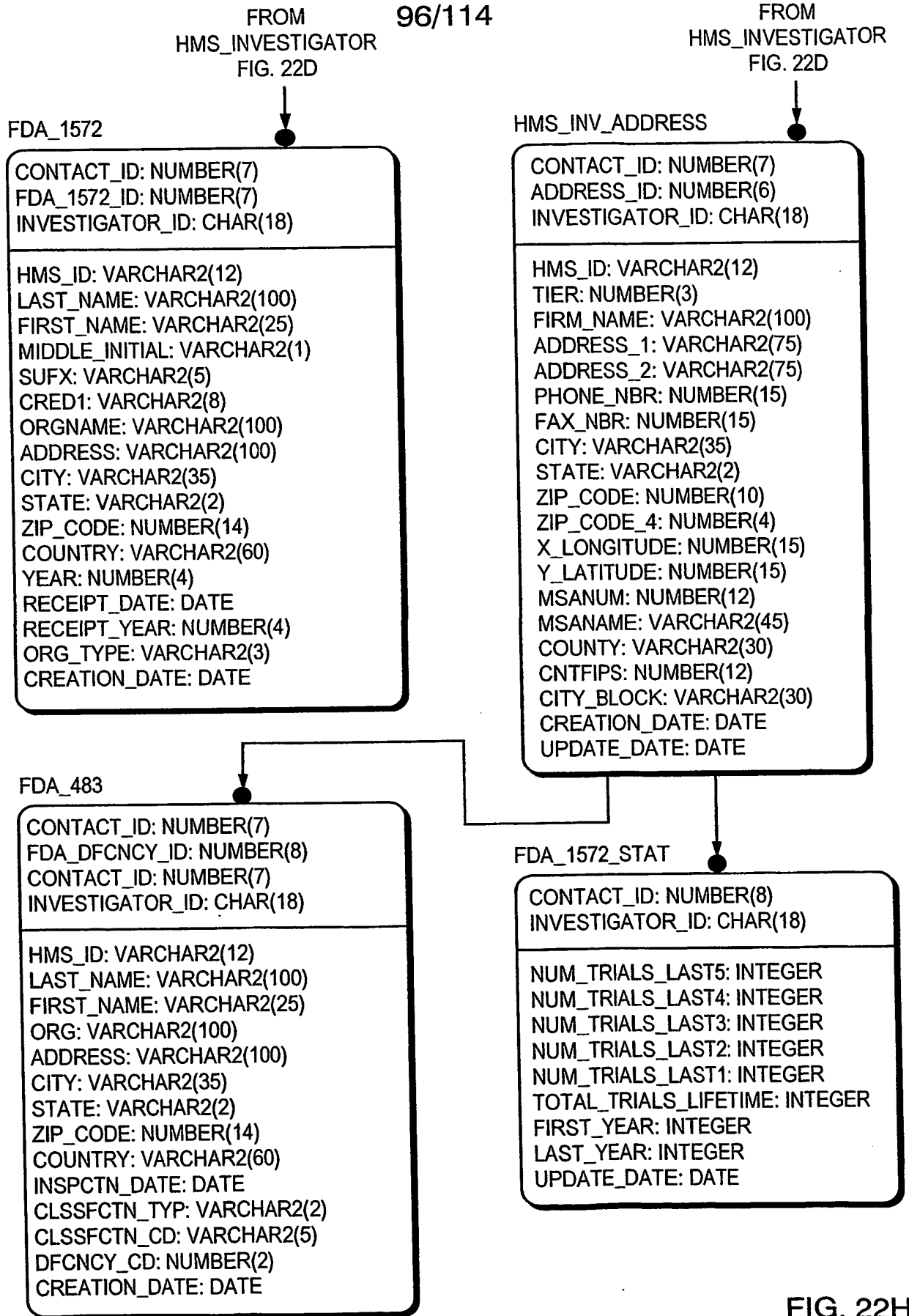


FIG. 22H

97/114

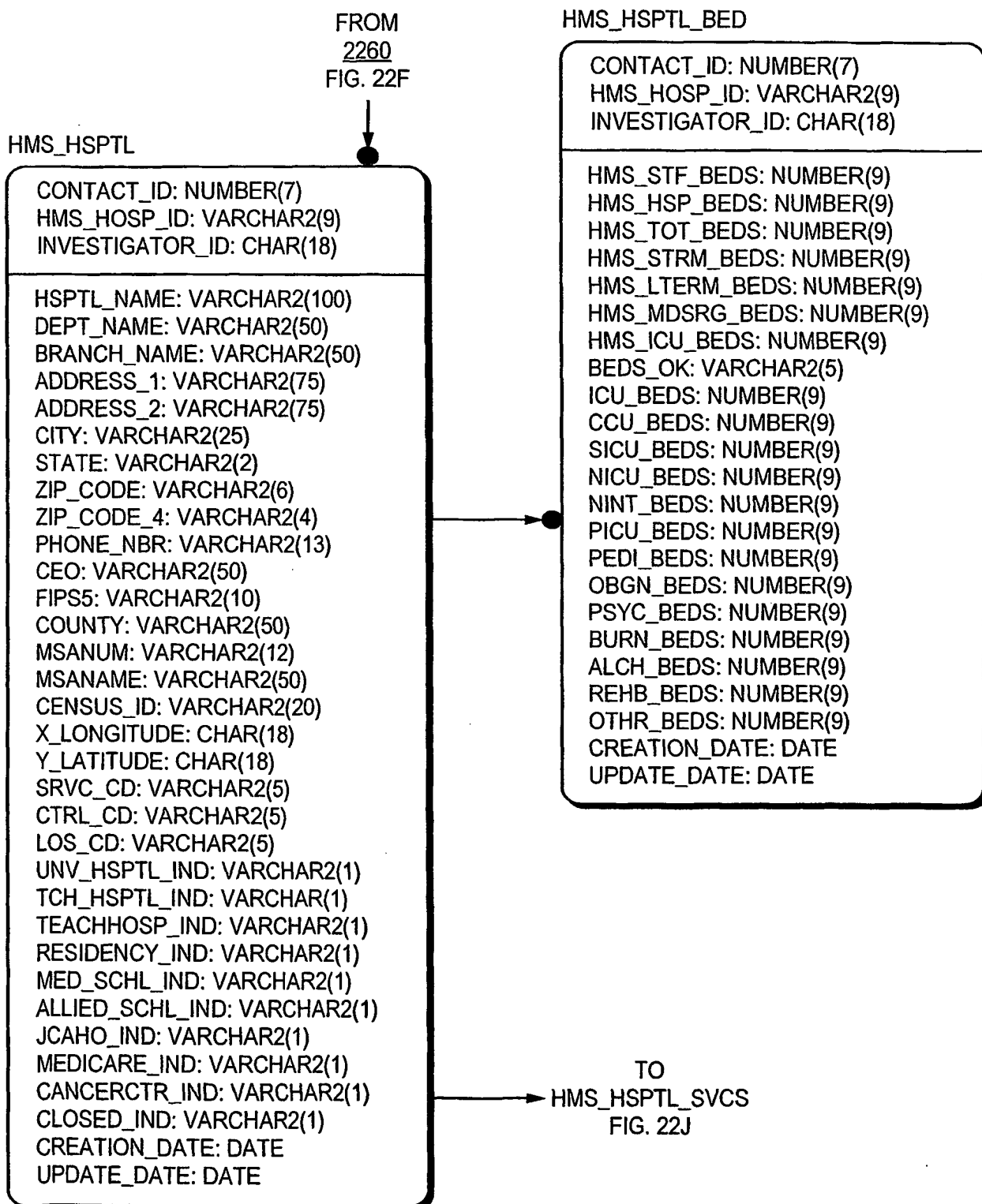


FIG. 22I

98/114

HMS\_HSPTL\_SVCS

FROM  
HMS\_HSPTL  
FIG. 22I

CONTACT\_ID: NUMBER(7)  
HMS\_HOSP\_ID: VARCHAR2(9)  
INVESTIGATOR\_ID: CHAR(18)

AIDS\_SVCS: VARCHAR2(1)  
ANSTH\_SVCS: VARCHAR2(1)  
ANGPLSTY\_SVCS: VARCHAR(1)  
BLOODBK\_SVCS: VARCHAR(1)  
BMTRNSPL\_SVCS: VARCHAR2(1)  
BURNCTR\_SVCS: VARCHAR2(1)  
CRDCTH\_SVCS: VARCHAR2(1)  
CVSRGY\_SVCS: VARCHAR2(1)  
CHIRO\_SVCS: VARCHAR2(1)  
CLPSY\_SVCS: VARCHAR2(1)  
CT\_SVCS: VARCHAR2(1)  
DENTL\_SVCS: VARCHAR2(1)  
ULTRSND\_SVCS: VARCHAR2(1)  
DIETRTY\_SVCS: VARCHAR2(1)  
ECARD\_SVCS: VARCHAR2(1)  
ECONV\_SVCS: VARCHAR2(1)  
EMRGCY\_SVCS: VARCHAR2(1)  
ESWL\_SVCS: VARCHAR2(1)  
LABAN\_SVCS: VARCHAR2(1)  
HEART\_SVCS: VARCHAR2(1)  
HRTLUNG\_SVCS: VARCHAR2(1)  
HEMDIAL\_SVCS: VARCHAR2(1)  
HOMCRE\_SVCS: VARCHAR2(1)  
HOSPCE\_SVCS: VARCHAR2(1)  
CCU\_SVCS: VARCHAR2(1)  
ICU\_SVCS: VARCHAR2(1)  
KIDNEY\_SVCS: VARCHAR2(1)  
LABCLNC\_SVCS: VARCHAR2(1)  
LIVER\_SVCS: VARCHAR2(1)  
LUNG\_SVCS: VARCHAR2(1)  
MEGVRAD\_SVCS: VARCHAR2(1)  
NEONUNT\_SVCS: VARCHAR2(1)  
NICU\_SVCS: VARCHAR2(1)  
MRI\_SVCS: VARCHAR2(1)  
NEURO\_SVCS: VARCHAR2(1)  
NSURG\_SVCS: VARCHAR2(1)  
NUCMED\_SVCS: VARCHAR2(1)  
OBSRVA\_SVCS: VARCHAR2(1)  
OBSTE\_SVCS: VARCHAR2(1)  
OCCTH\_SVCS: VARCHAR2(1)  
OPNHT\_SVCS: VARCHAR2(1)

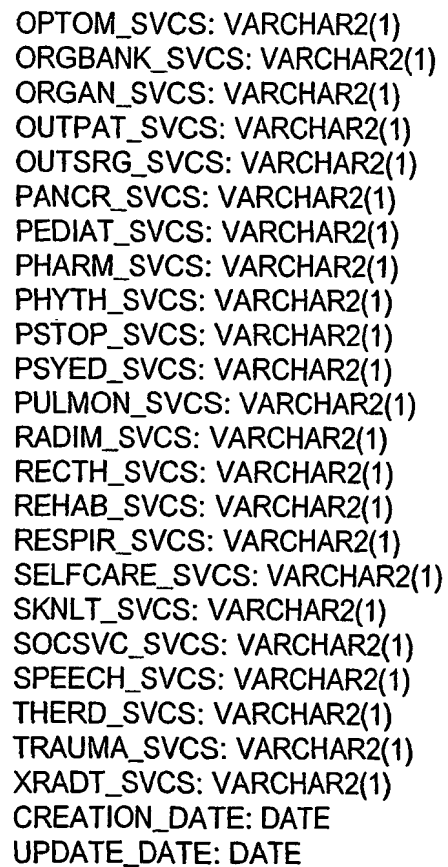
TO FIG. 22K

FIG. 22J

99/114

HMS\_HSPTL\_SVCS (CONT'D)

FROM FIG. 22J



OPTOM\_SVCS: VARCHAR2(1)  
ORGBANK\_SVCS: VARCHAR2(1)  
ORGAN\_SVCS: VARCHAR2(1)  
OUTPAT\_SVCS: VARCHAR2(1)  
OUTSRG\_SVCS: VARCHAR2(1)  
PANCER\_SVCS: VARCHAR2(1)  
PEDIAT\_SVCS: VARCHAR2(1)  
PHARM\_SVCS: VARCHAR2(1)  
PHYTH\_SVCS: VARCHAR2(1)  
PSTOP\_SVCS: VARCHAR2(1)  
PSYED\_SVCS: VARCHAR2(1)  
PULMON\_SVCS: VARCHAR2(1)  
RADIM\_SVCS: VARCHAR2(1)  
RECTH\_SVCS: VARCHAR2(1)  
REHAB\_SVCS: VARCHAR2(1)  
RESPIR\_SVCS: VARCHAR2(1)  
SELFCARE\_SVCS: VARCHAR2(1)  
SKNLT\_SVCS: VARCHAR2(1)  
SOC SVC\_SVCS: VARCHAR2(1)  
SPEECH\_SVCS: VARCHAR2(1)  
THERD\_SVCS: VARCHAR2(1)  
TRAUMA\_SVCS: VARCHAR2(1)  
XRADT\_SVCS: VARCHAR2(1)  
CREATION\_DATE: DATE  
UPDATE\_DATE: DATE

FIG. 22K

100/114

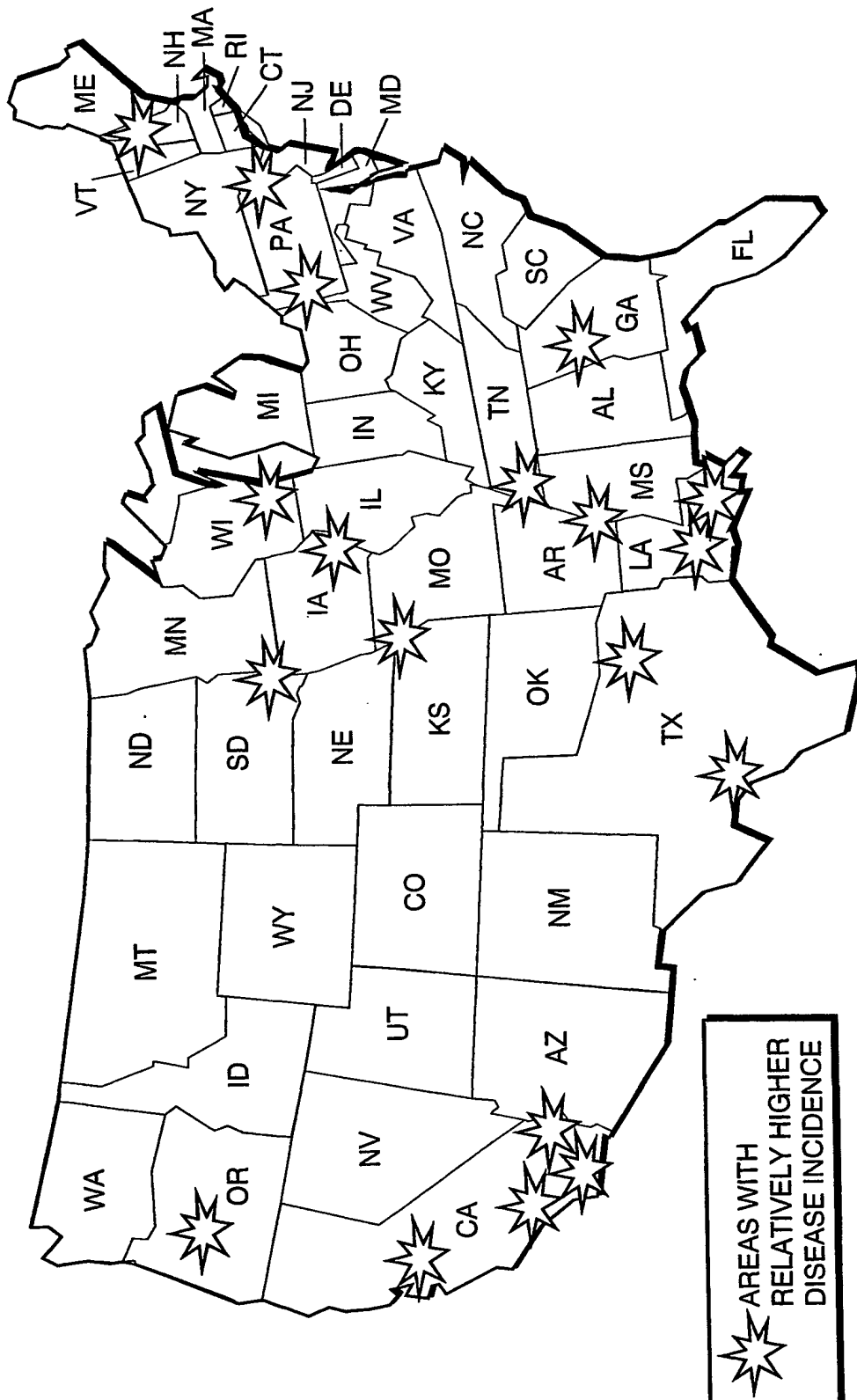


FIG. 22L



101/114

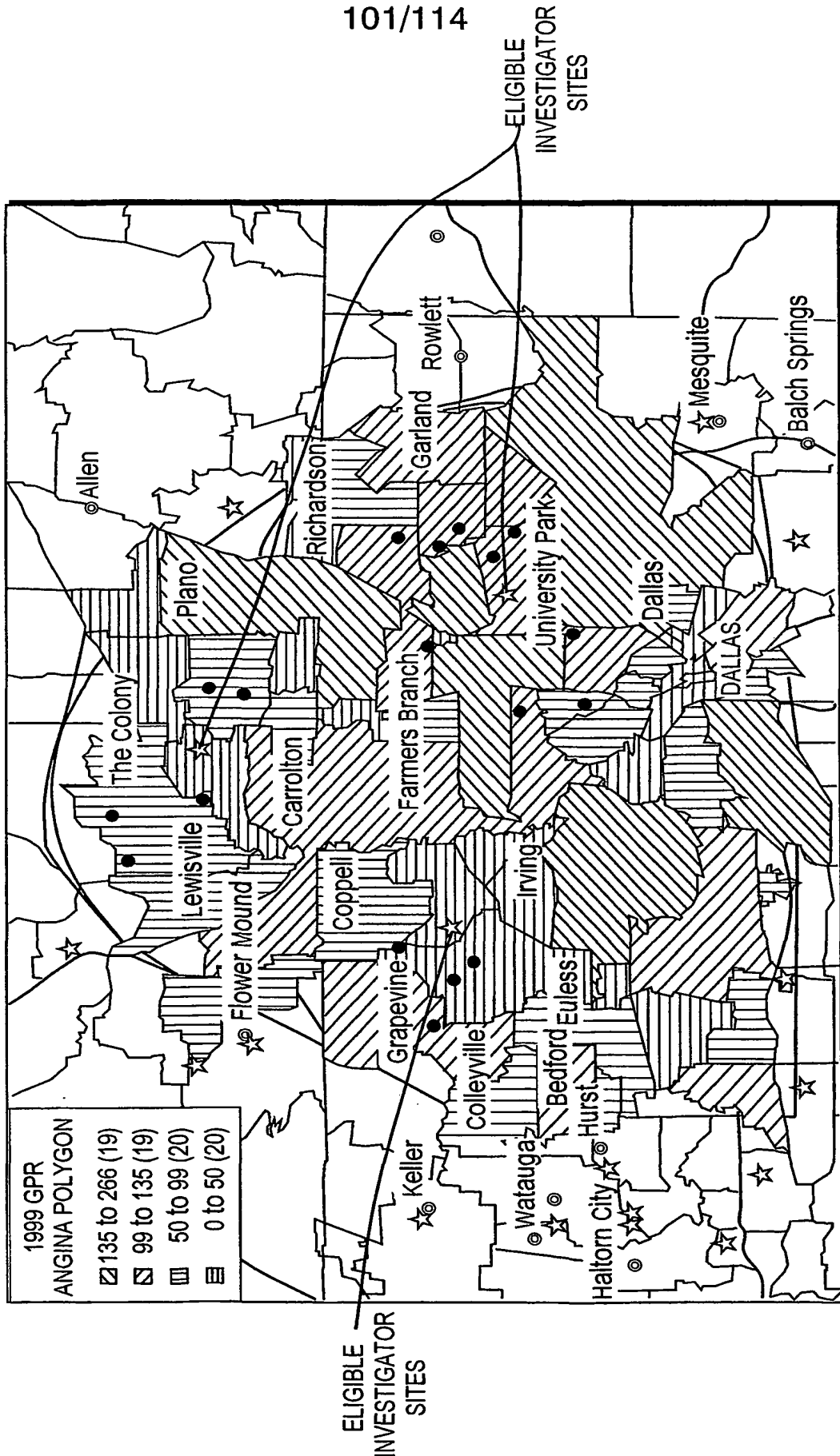


FIG. 22M

102/114

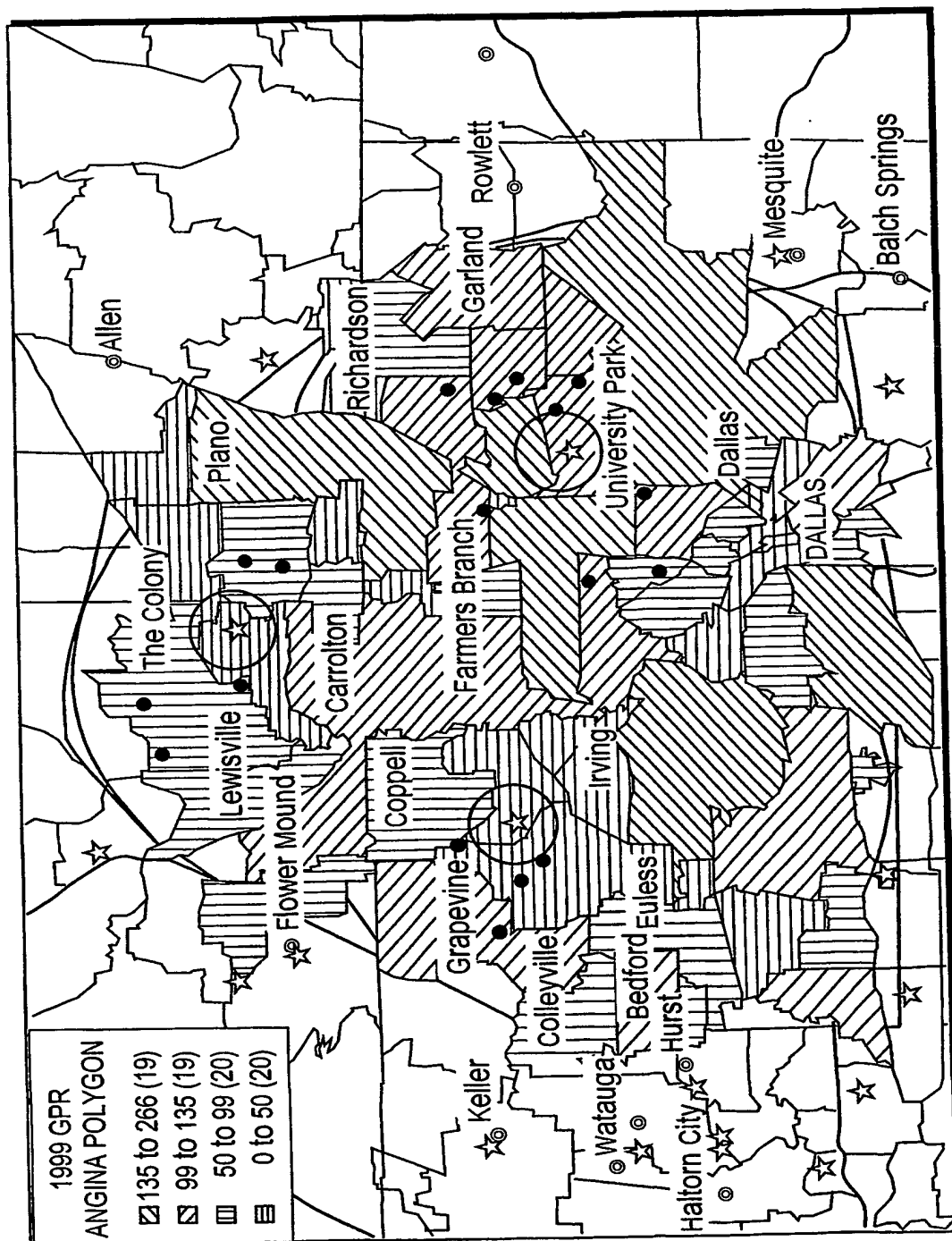


FIG. 22N

103/114

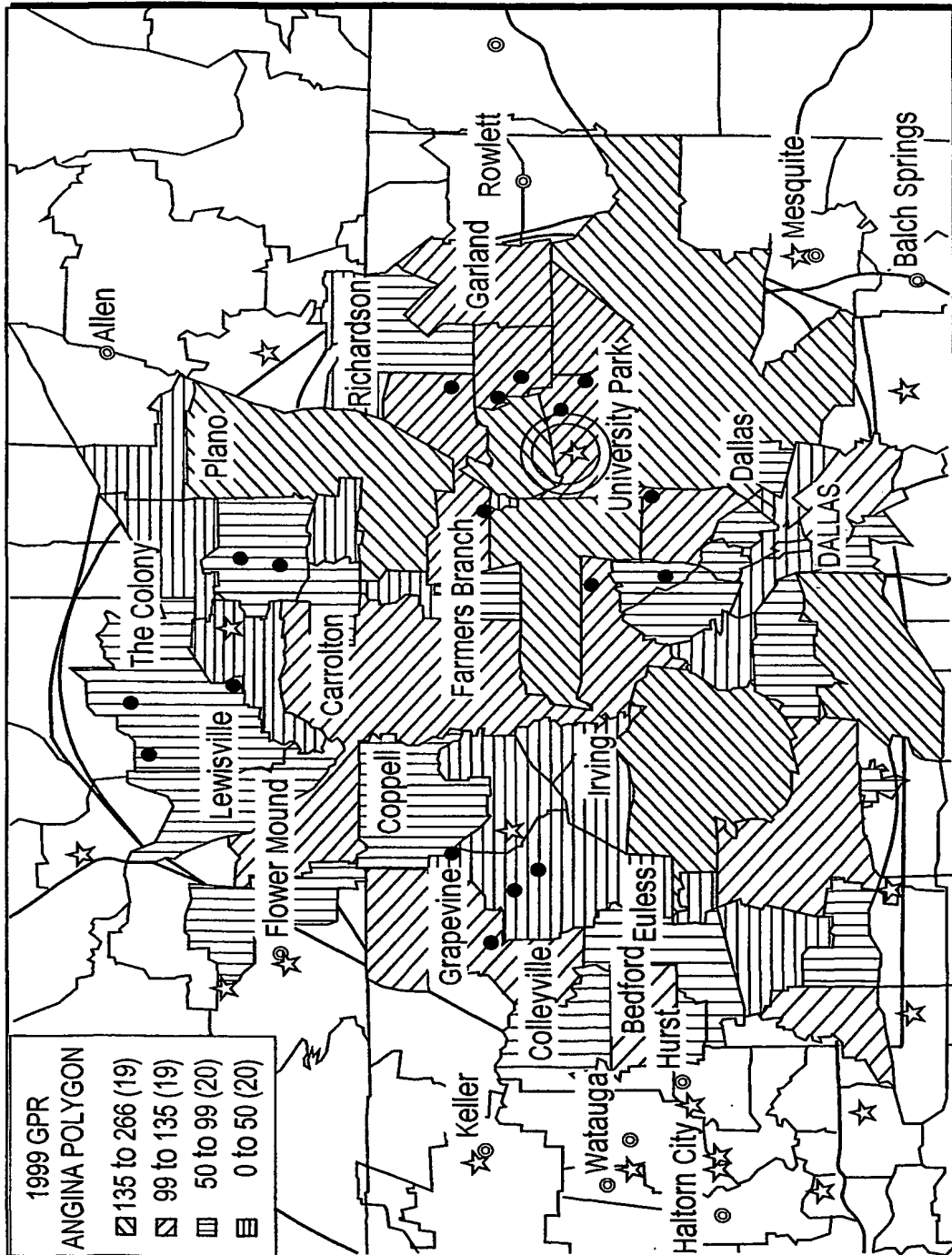


FIG. 220

104/114

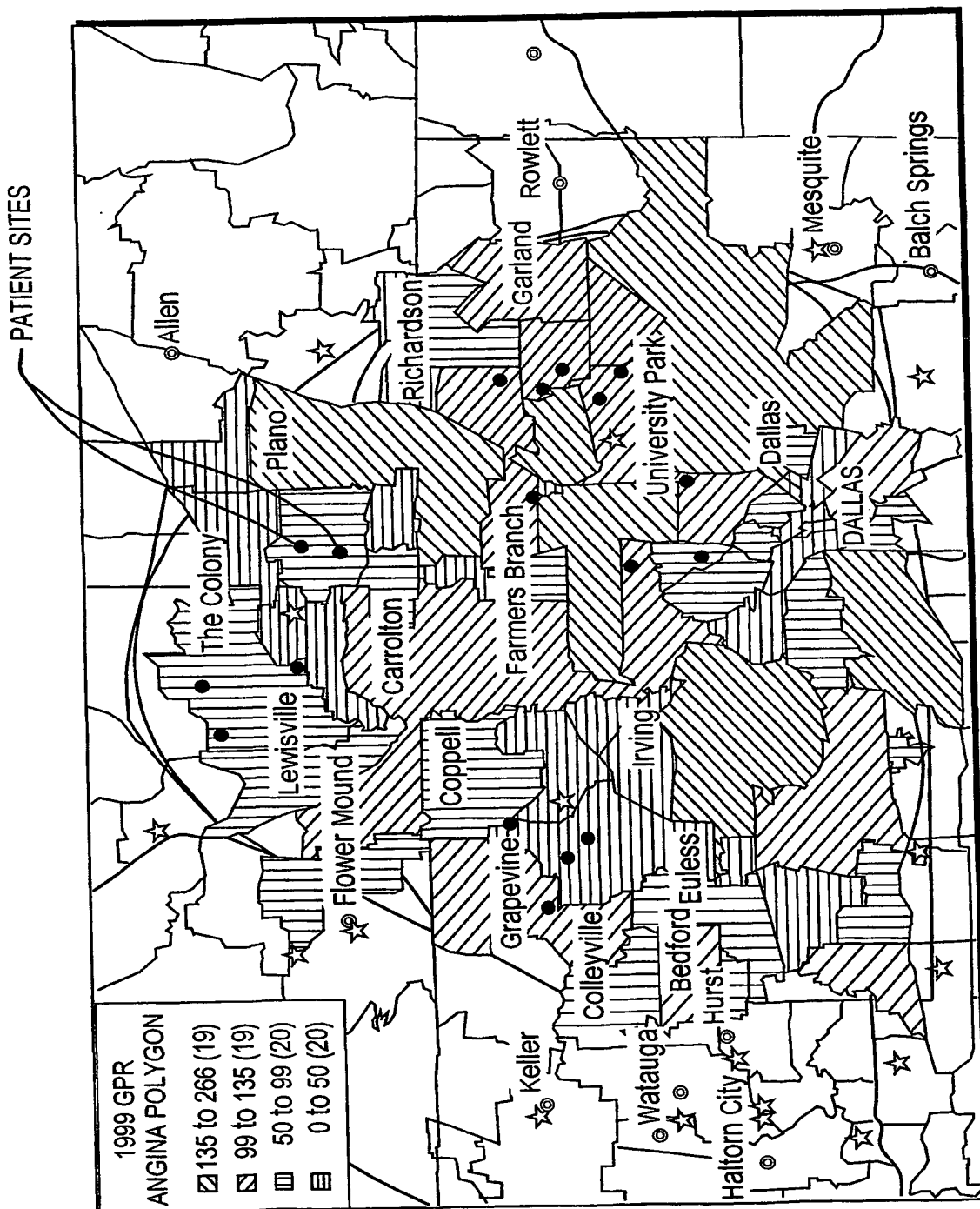



FIG. 22P

105/114



Smith, John

Specialty Cardiovascular Disease

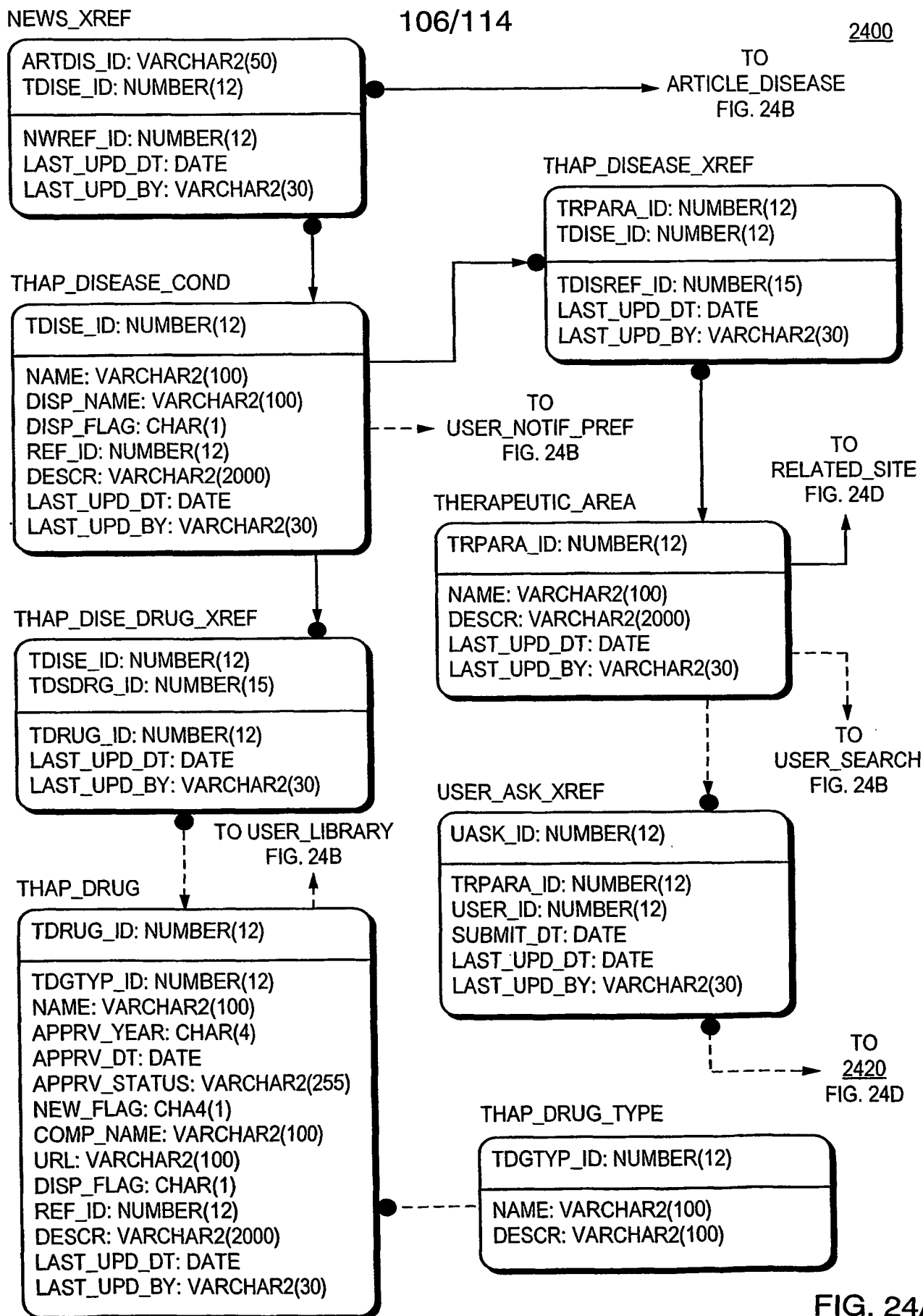
Internal Medicine

Contact Information	Primary Research Facility	Study Staff	Trial Experience	Provider	Hospital	Prismatic View
Yellow = ABC Pharma Trial						
Indication	Start Date	Enrollment Commitment	Evaluable Patients	Timeframe (months)	Enrollment Percentage	ABC Pharma Rank
APT	1/15/2001	12	8	12	70%	4
CHF	11/1/2000	10	9	9	90%	2302
CHF	10/5/2000	10	9	9	90%	
CHD	7/1/2000	8	3	6	40%	2
CAD	6/1/1999	15	12	6	80%	2304
CHT	2/15/1999	8	7	10	90%	
CHF	3/1/1998	10	8	12	80%	4
CHD	3/22/1997	6	4	10	60%	3
CHD	6/1/1996	8	6	10	80%	

AGGREGATED  
DATA  
2302

DATA  
SUPPLIED  
BY SPONSOR  
VIEWING  
SCREEN  
2304

FIG. 23



107/114

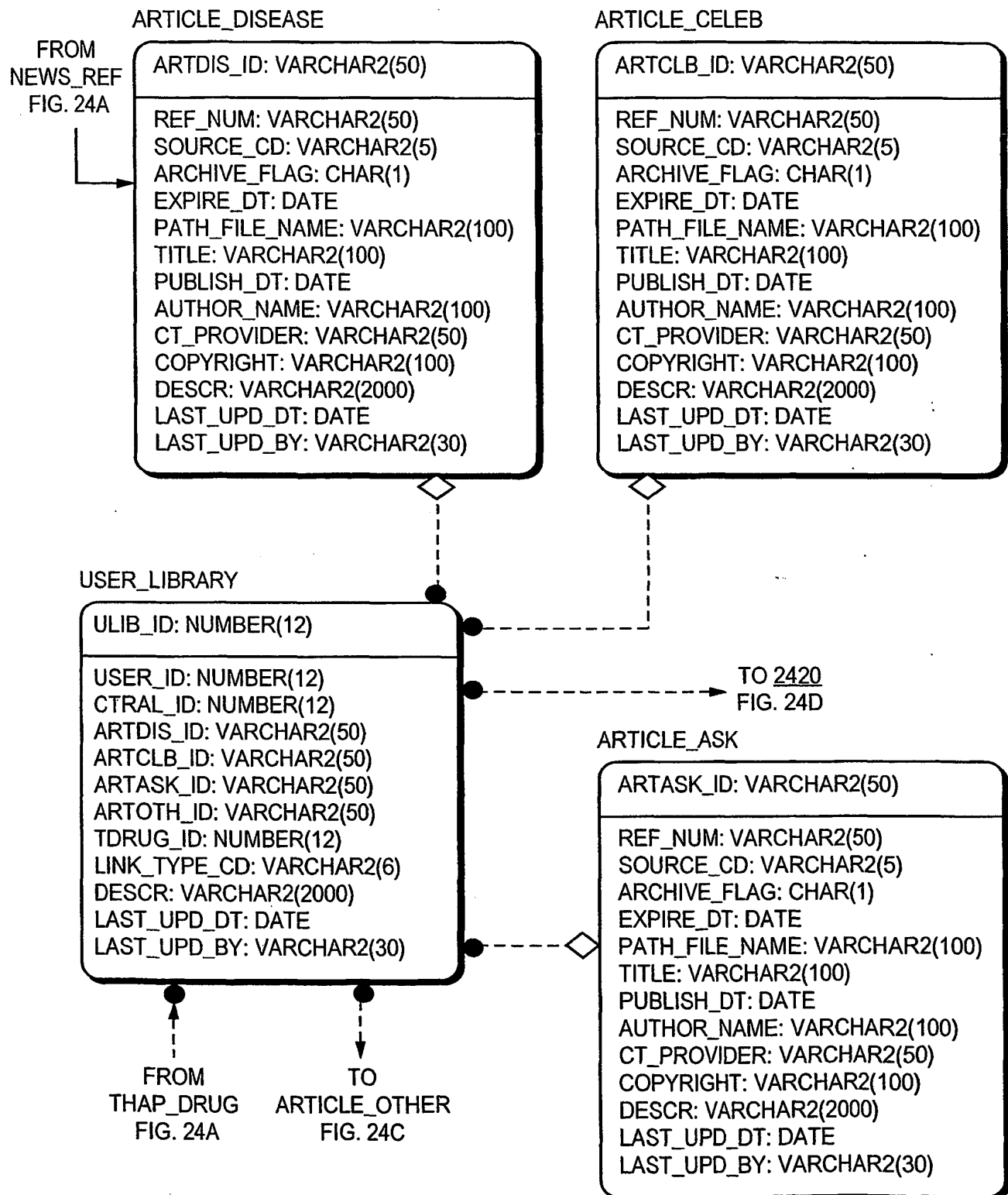


FIG. 24B

108/114

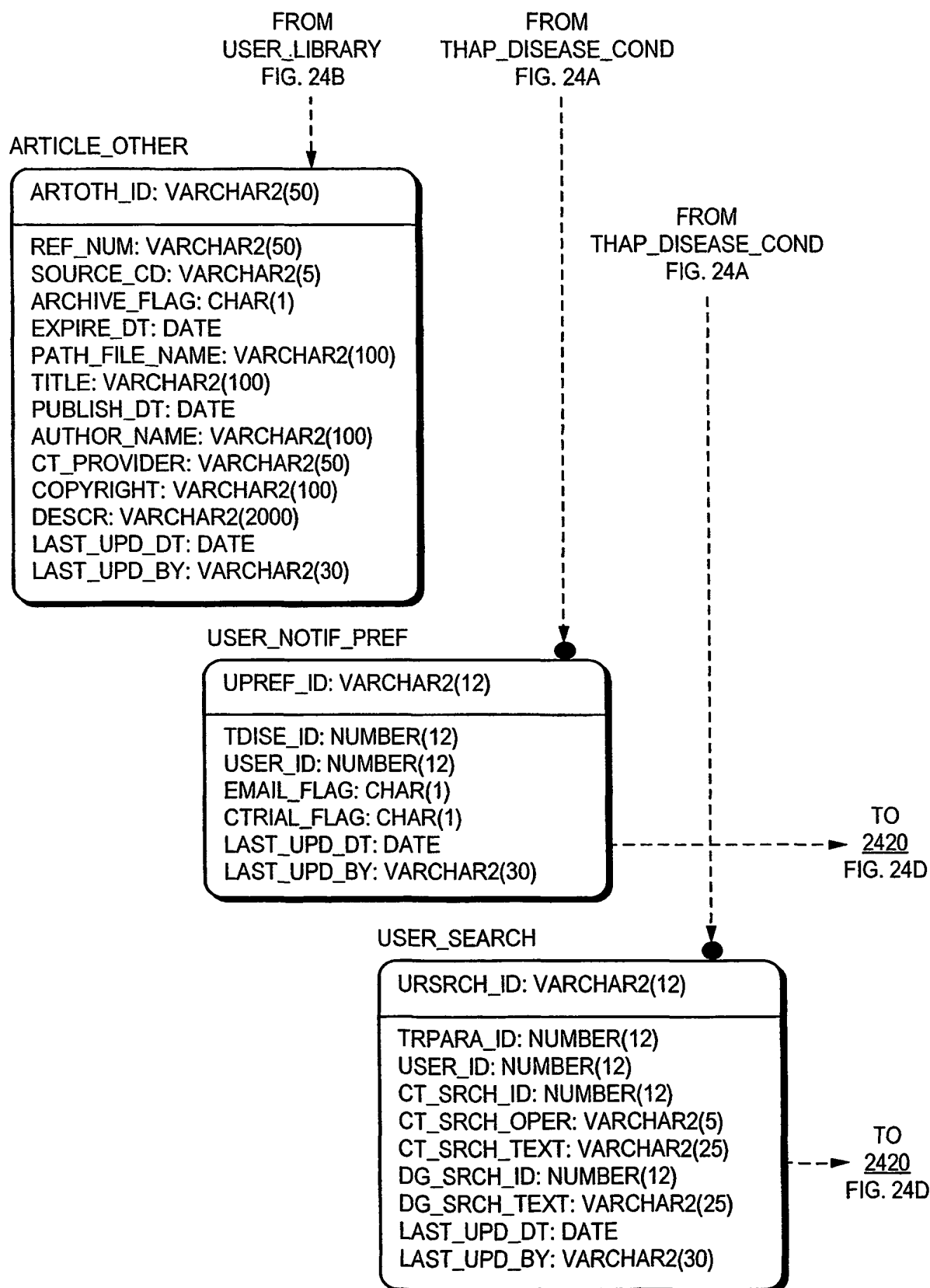


FIG. 24C  
SUBSTITUTE SHEET (RULE 26)



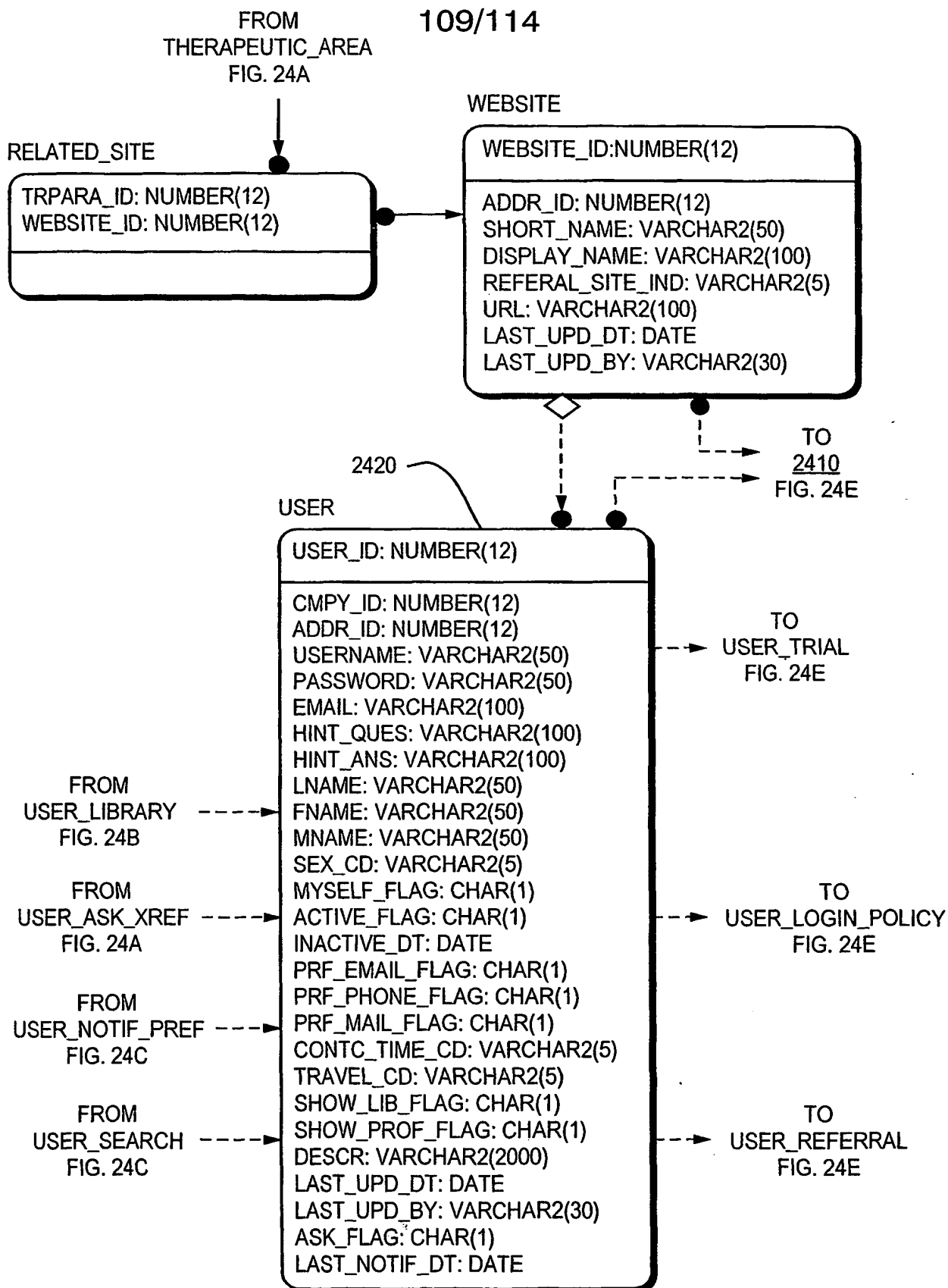
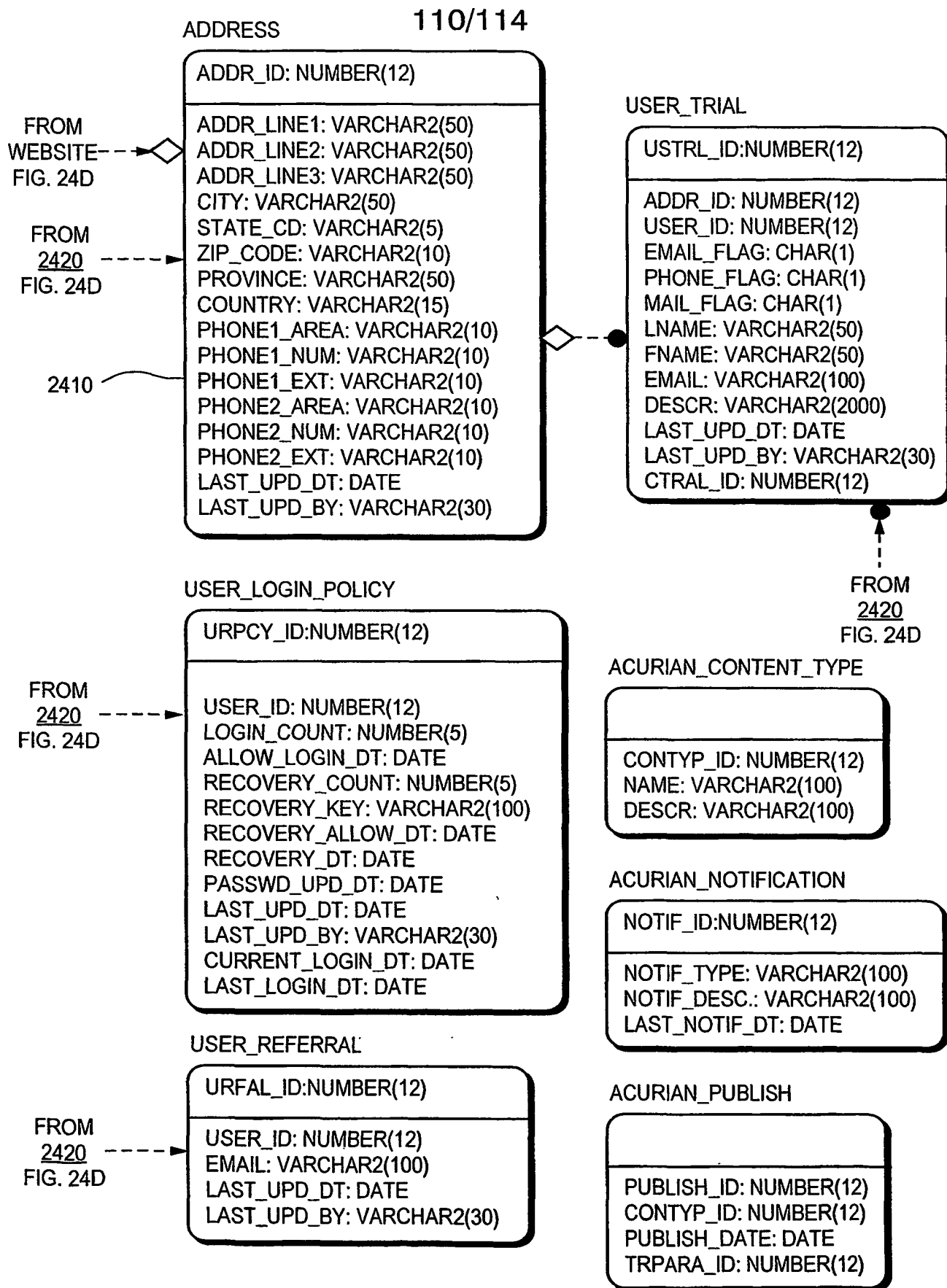


FIG. 24D



**FIG. 24E**  
**SUBSTITUTE SHEET (RULE 26)**

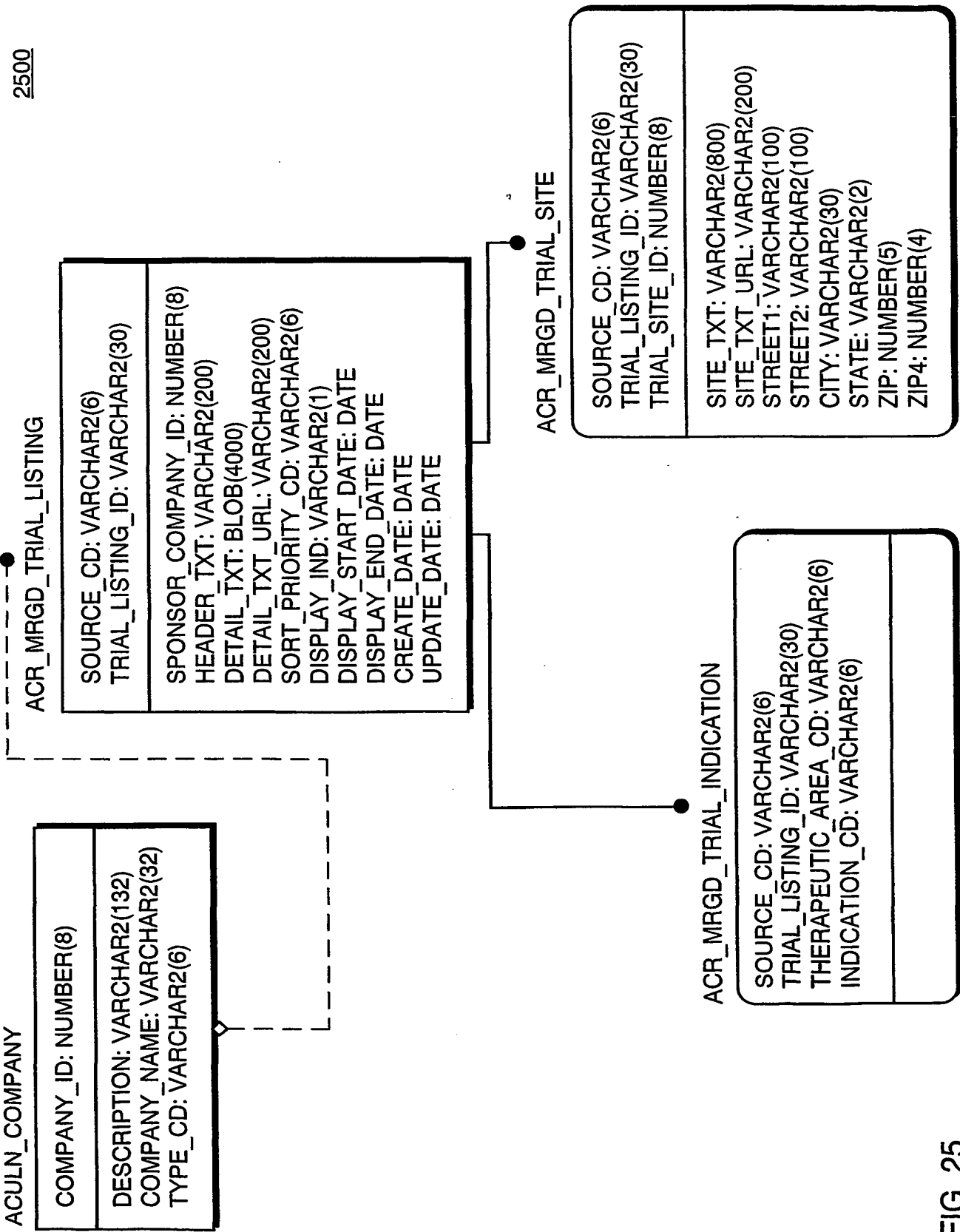


FIG. 25

112/114

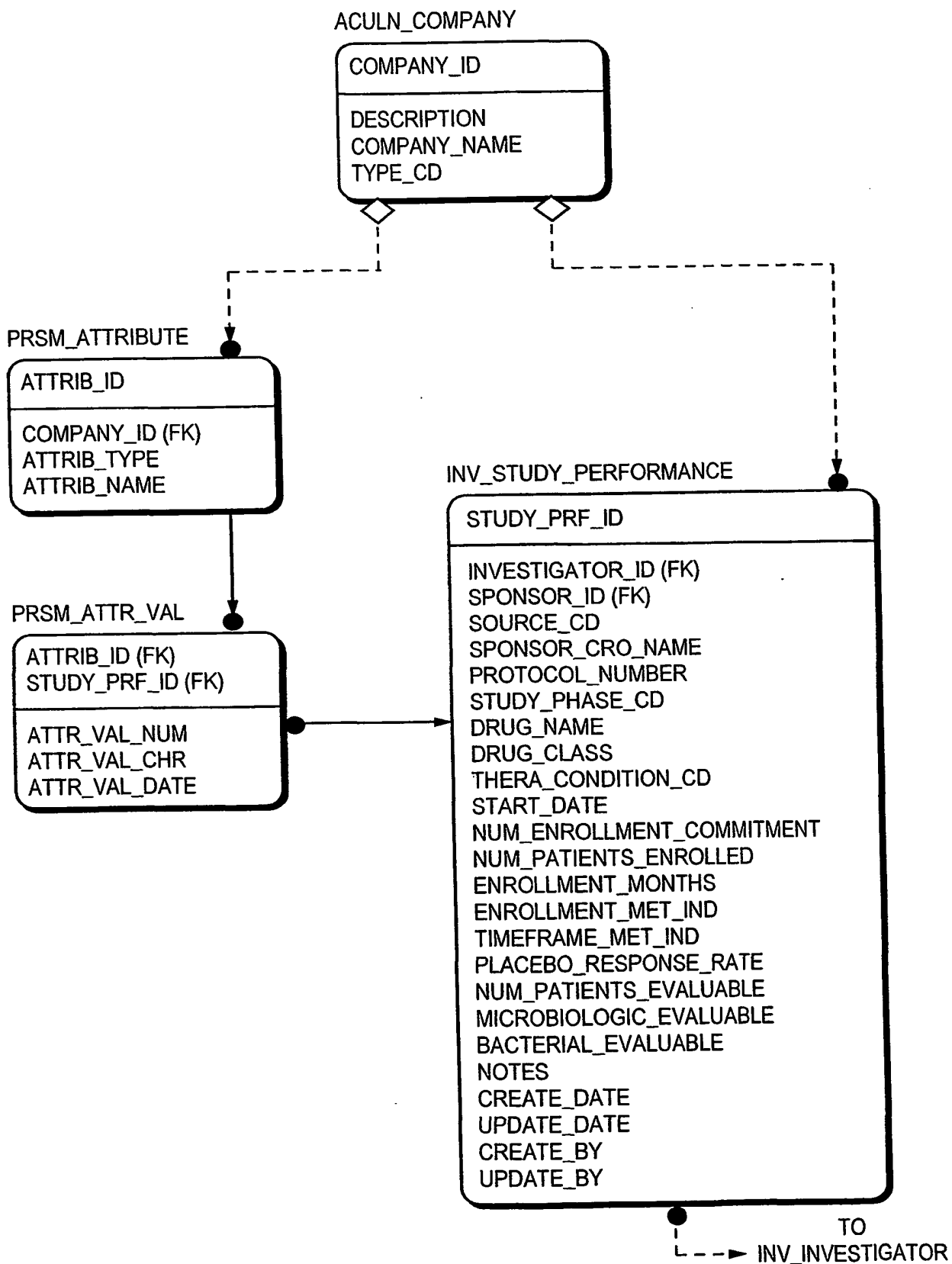



FIG. 26A

SUBSTITUTE SHEET (RULE 26)

113/114

INV\_INVESTIGATOR

FROM  
INV\_STUDY\_PERFORMANCE - - - ->   
FIG. 26A

INVESTIGATOR\_ID

SOURCE\_CD  
HMS\_ID  
FIRST\_NAME  
MIDDLE1  
MIDDLE2  
LAST\_NAME  
SUFFIX  
COUNTRY  
SOC\_SEC\_NBR  
IND\_UPIN  
SEX  
DOB  
MED\_SCHOOL\_CD  
GRADUATION\_YEAR  
RSDNCY\_ORG  
RSDNCY\_CITY  
FLLWSHP\_ORG  
FLLWSHP\_CITY  
DEGREE1  
DEGREE2  
PHONE\_NBR  
PHONE\_EXTENSION  
FAX\_NBR  
EMAIL  
CREDENTIAL  
DELETE\_REASON\_CD  
DELETE\_REQUEST\_DATE  
WRONG\_NUMBER\_IND  
CV\_RECEIVED\_DATE  
QUESTIONNAIRE\_RETURNED\_DATE  
SMO\_RELATIONSHIP\_CD  
PRACTICE\_TYPE\_CD  
PRIMARY\_IN\_OUT\_CD  
CRO\_NUM\_DAYS\_NOTICE  
PHASE1\_EXPERIENCE\_IND  
PHASE2\_EXPERIENCE\_IND  
PHASE3\_EXPERIENCE\_IND  
PHASE4\_EXPERIENCE\_IND  
PATIENT\_DATABASE\_IND  
SOFTWARE\_PACKAGE\_NAME  
CREATE\_DATE  
UPDATE\_DATE  
CREATE\_BY  
UPDATE\_BY

FIG. 26B

SUBSTITUTE SHEET (RULE 26)

114/114

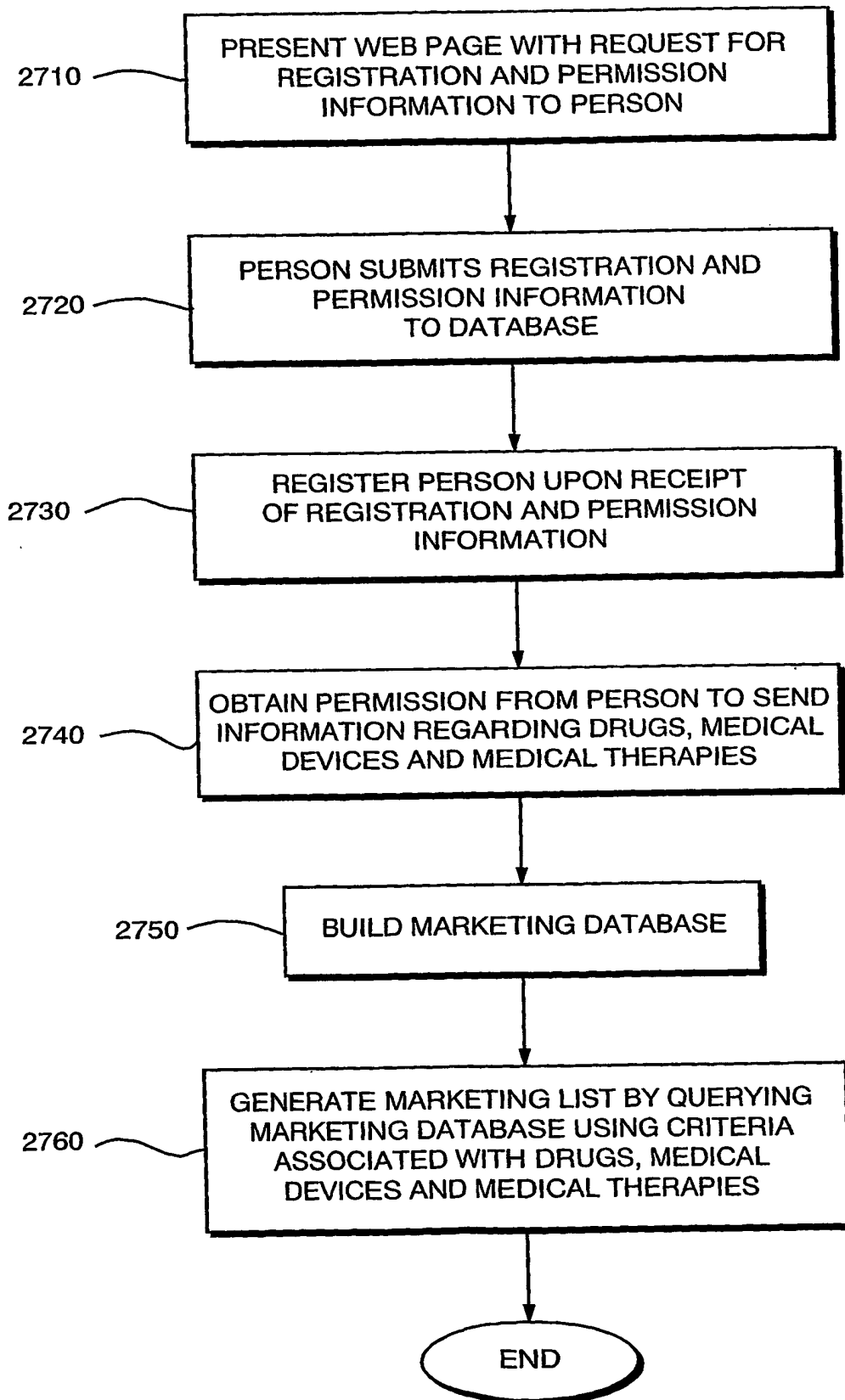


FIG. 27  
SUBSTITUTE SHEET (RULE 26)

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US01/02936**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :G06F 17/60

US CL :705/3

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 705/3, 2; 600/300

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST search (US Patents, EPO, JPO, Derwent), DIALOG search (business and marketing databases), PROQUEST search (all databases), see attached.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- A	US 5,991,731 A (COLON et al.) 23 November 1999, col. 1, lines 48-51, col. 4, lines 49-53, col. 6, lines 22-30 and col. 7, lines 46-54).	1, 16, and 26 ----- 2-15, 17-25, and 27-120
A	US 5,734,883 A (UMEN et al) 31 MARCH 1998, see abstract)	1-120
A	ANONYMOUS. Public CROs: Clinicor Inc. R&D Directions. September 1999. Vol. 5 .No. 8. pp. 91.	1-120

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

10 MARCH 2001

Date of mailing of the international search report

24 APR 2001

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

TARIQ HAFIZ

Telephone No. (703) 305-9643

Form PCT/ISA/210 (second sheet) (July 1998)\*

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US01/02936

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	ANONYMOUS. Dialog file 16 (Gale group PROMT(R)). No. 6439375. drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patients on the Internet. PR Newswire. 3 pages.	1-120
A	ZOELLER, JANICE. Surfing for complementary info. American Druggist. September 1999. Vol. 216. No. 9. pp. 15.	1-120
A	MCCRAY, ALEXA T. A national resource for information on clinical trials. National Forum. September 1999. Vol. 79. No. 3. pp. 19-21.	1-120
A	UKENS, CAROL. CenterWatch is hub of clinical trials Web sites. Drug Topics. 19 April 1999. Vol. 143. No. 8. pp. 112.	1-120

Form PCT/ISA/210 (continuation of second sheet) (July 1998)\*



**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☒ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**

**THIS PAGE BLANK (USPTO)**